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Analytical Studies
for the U.S.
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VOLUME IIa
**Decision Making
in the Environmental
Protection Agency**
CASE STUDIES

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for the
Committee on Environmental Decision Making

Commission on Natural Resources
National Research Council

NATIONAL ACADEMY OF SCIENCES
Washington, D.C. 1977

NOTICE

This report consists of case studies prepared for the Committee on Environmental Decision Making. The views expressed herein are those of the authors and do not necessarily represent those of the Committee or the National Research Council.

The Committee's project plan was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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PREFACE

The seven case studies in this volume were intended to acquaint the Committee on Environmental Decision Making with the complexities of EPA policy formulation for a range of actual past decisions. Along with presentations to the Committee by individuals directly involved in EPA decisions and a set of research reports (some of which are compiled in the companion Volume II B) by Committee members, staff and consultants, the cases supplied the empirical data considered in reaching the findings and recommendations of Decision Making in the Environmental Protection Agency (NRC 1977).

The overall EPA study project originated in June 1973 when the Subcommittee on Agriculture-Environmental, and Consumer Protection of the Appropriations Committee of the U.S. House of Representatives held extensive hearings on the activities of EPA. The ensuing appropriations bill for fiscal year 1974 directed the Agency to contract with the National Academy of Sciences for a series of analytical advisory studies. EPA and the Academy agreed upon a program that would respond to the Congressional intent by exploring two major areas: the process of acquisition and use of scientific and technical information in environmental regulatory decision making, and the analysis of selected current environmental problems. The Academy directed the National Research Council to formulate an approach to the analytical studies and the National Research Council in turn designated the Commission on Natural Resources as the unit responsible for supervising the program. Within the resulting program of studies, the Committee on Environmental Decision Making was given the specific purpose of examining the process of decision making at the Environmental Protection Agency in order to make recommendations for the effective use of scientific and technical information in making regulatory decisions.

The CEDM case studies were selected by their authors with the guidance of the Committee and the concurrence of EPA. The sample of cases was selected to be representative of the EPA programs; accordingly, decisions were selected for three major EPA program areas, air pollution (two cases), water pollution (two cases), and pesticides/toxic substances (three cases). The Agency stipulated that case studies could not be conducted for decisions that were

subject to possible litigation but did not otherwise constrain case selection.

The case studies were prepared by CEDM staff members and are based on available decision documents and interviews with individuals inside and outside EPA who had first-hand familiarity with the subject decision. The Agency cooperated fully with the fact-finding effort. Most of the case studies were reviewed in draft form by appropriate EPA officials and informed outside participants. The cases were submitted to CEDM in the summer of 1976 and were revised for this printing in early 1977.

The cases vary widely in style and content according to the background and interests of the writers. The common objective was to reflect the technical and organizational complexity of actual decisions; beyond that, case writers were left free to emphasize problems and concepts particularly well illuminated in their cases.

The staff expresses enthusiastic appreciation for the wit, charm, competence, and cheer of Christina Olson and Elizabeth Panos.

REFERENCE

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INDIRECT SOURCE REVIEW: ROLLING WITH THE PUNCHES

Richard W. Lowerre¹

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In 1973 EPA developed a traffic control strategy, known as indirect source review (ISR), for the purpose of reducing the adverse impact of automobile emissions on the air we breathe. ISR was a novel approach for controlling certain motor vehicle pollutants by controlling motor vehicle activity. By 1975, however, this approach was essentially barred.

Seldom in EPA's history has any program been so influenced by forces outside the Agency. Although no single event or party can be pointed to as having caused the suspension of the ISR program, EPA's inability to provide both a demonstration of the benefits to be derived from ISR and the scientific documentation necessary to defend the program certainly contributed. ISR was left open to attack in the courts, Congress, and other public forums. Even now, as Congress reconsiders the Clean Air Act, the value of ISR remains uncertain.

This case study will trace the history of indirect source review as it applied to parking facilities. Because the decision-making process spanned three years and countless decisions, some issues will be treated only briefly. EPA's regulations for parking management and for indirect sources such as airports and highways will not be discussed.

I. THE RISE AND FALL OF INDIRECT SOURCE REVIEW

The 1970 Amendments to the Clean Air Act direct EPA to set national standards for ambient air quality and to ensure the attainment and maintenance of those standards through implementation programs developed and enforced by the states.² Each state is required to submit a proposed state implementation plan (SIP) to EPA for a determination of whether the programs in the SIP adequately provide for attainment and maintenance of air quality standards. If a state fails to submit a plan, or if any part of the plan is disapproved, EPA must promulgate a substitute regulation.

For example, in 1971 EPA established a national primary ambient air quality standard for particulate matter for the purpose of protecting public health.³ Most states have prepared state implementation plans (SIPs) which provide limitations on any stationary source of particulates, such as a municipal incinerator, to ensure that the national ambient standard is not violated.⁴ Typical control

strategies involve numerical emission limitations on the amount of particulate matter discharged from the stacks or opacity limits on the plumes from the stacks.

The Clean Air Act also gives EPA the primary role in enforcing emission limitations on pollutants from mobile sources such as motor vehicles.⁵ This authority has lead to the current use of catalytic converters on new automobiles. EPA emission limitations, however, apply only to new vehicles, and until attrition reduces the number of older, uncontrolled vehicles, the impact of vehicle emission limitations will not be significant. Furthermore, several pollutants, such as carbon monoxide and hydrocarbons, which are discharged from stationary sources and are subject to EPA's national ambient air quality standards, are also emitted from motor vehicles. Emissions from cars and trucks alone are capable of causing violations of these standards even when there is little or no added pollution from stationary sources. As a result, limitations on stationary sources will not always provide the controls needed for attaining and maintaining certain air quality standards.

Because motor vehicle emissions are a major contributor to the degradation of air quality, especially in large cities, EPA is confronted with the problem of reducing the impact of vehicle emissions. In addition, local "hot spots" or sites of high pollution concentrations that result from the short term build up of vehicle emissions in congested areas can cause serious pollution problems. Dispersion of the emissions often reduces or eliminates "hot spots"; however, at points close to the sources the public can be exposed to concentrations of pollutants that exceed the air quality standards. Even vehicles with catalytic converters can create "hot spot" conditions.

Over the period from 1972 to 1975, EPA attempted to solve the problems of emissions from older vehicles and the problems of local concentrations of emissions by requiring that states develop controls on traffic flow and congestion. Indirect source review programs were developed, along with certain provisions of transportation control plans, as control strategies analogous to the traditional pollution control programs for stationary sources. Indirect sources are defined as facilities, such as buildings with related parking lots, that "attract increased vehicular activity and...may prevent or interfere with the attainment of an air quality standard"⁶ because of the increased vehicular activity. EPA's ISR program required that an application for review be submitted for any new or modified indirect source. The enforcing agency (state or EPA regional office) would review the application to determine whether vehicle emissions at the proposed site, when added to local background levels, would create violations or exacerbate existing violations of the ambient air quality standards.

Like new or modified stationary sources that are reviewed to examine the anticipated impact of the pollutants emitted directly, new or modified indirect sources could be reviewed to examine the effects of anticipated pollutants emitted by motor vehicles attracted to such sources.

A. The Development of Indirect Source Review Regulations

In 1971 EPA had established primary ambient air quality standards for particulate matter, sulfur oxides, carbon monoxide, hydrocarbons, nitrogen dioxide, and photochemical oxidants,⁷ and had issued guidelines for the development of SIPs.⁸ In 1972 EPA decided that it would not be feasible to attain the ambient standards for the vehicle-related contaminants, carbon monoxide (CO) and photochemical oxidants, by 1975, and EPA interpreted the Clean Air Act as allowing for delay in the attainment date.⁹ A delay would relieve the immediate need to develop traffic controls and postpone the attainment date for CO and oxidants standards to the middle of 1977. EPA recognized the need to develop some requirement for control of vehicle emissions in addition to limitations on new vehicles, but EPA's Air Program Office had very little information concerning the effects of traffic control programs on vehicle emissions and air quality.¹⁰

In the spring of 1972, an EPA memorandum indicated that many locations could not meet one or more of the ambient air quality standards without additional vehicle emission controls. The memorandum explained the current knowledge on the cost and effectiveness of traffic controls and suggested alternatives such as redesign of intersections for better traffic flow and parking restrictions or fees to reduce the number of vehicles in congested areas.¹¹ Parking lot review, such as would be required by indirect source regulations, was not included. After the May, 1972 decision to delay attainment dates for CO and oxidants, an attorney for EPA's Office of General Counsel (OGC) noted that something needed to be done about traffic related pollution and that the Natural Resources Defense Council (NRDC) "has noted this omission and intends to raise this issue with the Agency."¹²

Indeed, NRDC did raise the issue in a U.S. Court of Appeals, challenging EPA's approval of SIPs that provided for the two year delay in the 1975 attainment date.¹³ The Court struck down the two year delays for CO and oxidants, finding that the Act requires EPA to make a state-by-state determination of the availability of and necessity for programs such as transportation control plans after a state has submitted a plan for approval.¹⁴ Thus, EPA could not give a blanket two year delay to all states before examining

the need for the delay in each state. As a result of this suit, EPA disapproved all SIPs in March of 1973 and required that states submit new plans containing programs directed at the control of traffic-related pollutants for the attainment and maintenance of air quality standards by 1975.¹⁵ EPA agreed with NRDC that no state SIP could adequately provide for maintaining the ambient standards unless it had a

provision for reviewing, and where necessary, preventing the construction or modification of facilities which were not harmful because of emissions emitted by them, but because of emissions resulting from activities associated with such new or modified facilities.¹⁶

At this time sources were to be reviewed for more than vehicle-related pollution effects. The siting of a new facility would require increased power generation and waste treatment capacity, and these "indirect" effects were to be examined in the review process.¹⁷ Review of indirect sources is now limited to the effects of increased vehicular activities on air quality standards. The review was designed to be one of a number of tools available to states for solving the vehicle-related pollution problems that were not going to be solved by direct control of emissions from motor vehicles. In its brief to the court, NRDC had suggested the idea of reviewing new construction in reference to the development of the controversial Hackensack Meadowlands in New Jersey, a proposed development of a sports complex and industrial park. ISR was, however, only a proposal, and there was little or no data on the air quality, economic, or social impact of such a program.¹⁸ EPA had to develop a method for the review of indirect sources and at the same time develop the supporting data to determine where ISR would be necessary for air quality control.

In February, 1973 EPA and NRDC agreed to a court approved time schedule for EPA action (see Table 1). Under this schedule EPA had to develop an ISR program and begin reviewing applications from developers for permits to construct facilities by the summer of 1974. To do so, EPA had to resolve quickly such issues as: what sources would be covered by the regulations, how could predictions be made about whether a violation would occur, would the states be able and willing to administer the program, and how could EPA get support or acceptance for the program from the industries regulated and the general public?

In March, 1973 EPA began gathering scientific data on the air quality impact and design criteria of parking lots and began developing ISR regulations. The preparation of regulations requiring states to develop ISR as part of their SIPs and of regulations establishing the federal program for

TABLE 1
TIMETABLE FOR DEVELOPMENT OF ISR

<u>Deadline</u>	<u>Action to be taken (actual date of action)</u>
MARCH 8, 1973	EPA must disapprove any state implementation plan failing to contain adequate provisions for maintenance of air quality standards. (All SIPs were disapproved on March 8.)
APRIL 18, 1973	EPA must publish proposed regulations requiring SIPs to contain ISR programs. (On April 18, the regulations were published.)
JUNE 18, 1973	EPA must publish final regulations requiring SIPs to contain ISR programs. (On June 18, the regulations were published.)
AUGUST 15, 1973	State must submit new SIPs to comply with the June 18 regulations. (No state complied on time, but eight states submitted plans in October, 1973.)
OCTOBER 15, 1973	EPA must approve or disapprove states' ISR programs, promulgate federal ISR regulation for any state that either fails to submit a plan or has its plan disapproved. (EPA proposed Federal regulations on October 30, 1973.)
DECEMBER 15, 1973	EPA must promulgate final Federal ISR regulations. (EPA promulgated "interim final regulations on February 25, 1974, and revised them on July 9, 1974.)

those states that failed to develop their own ISR program was not handled by the normal decision-making procedures within EPA. Instead of using the standard working group that is made up of representatives from each EPA office, EPA relied on the air programs office with assistance from the OGC. The Air Monitoring and Data Analysis Branch was asked to develop the scientific models needed for ISR, and the Office of Air Quality Planning and Standards (OAQPS) took the lead responsibility for drafting the regulations.

In March, 1973 EPA wanted to assist those states preparing revisions to their SIPs by providing the minimum criteria for ISR. The basis for such guidance, however, was not available. EPA, therefore, placed the burden on the states to plan their own ISR regulations at the same time EPA prepared the necessary data and models for the federal regulations. Assistance was offered to states as it became available; however, no state submitted a plan by the August, 1973 deadline. The states that finally did submit plans did so only after EPA had developed its program in October, 1973. It is the view of several EPA employees that the time schedule put much too great a burden on EPA and the states and made it impossible to develop and validate an ISR program before it was to become applicable to new sources.

EPA received an increasing number of negative comments during May and June of 1973. States were critical of the administrative burden, and industry was critical of the prospective costs. The League of Cities-Conference of Mayors was encouraging mayors to express their concern with the federal government taking land-use control from local governments. In addition, while some citizen groups reacted favorably, NRDC commented that the proposed ISR regulations were too weak and would not adequately ensure the maintenance of national ambient air quality standards as required by law and the court.

By the summer of 1973 EPA had made the initial determination to limit ISR to the control of CO. Carbon monoxide is amenable to localized impact analyses, and EPA assumed that the control techniques for CO would also be effective in reducing other pollutants of motor vehicles. Several other problems that arose at this time were not so easy for EPA to resolve. For example, a poll of state programs conducted by EPA's regional offices showed that many state agencies lacked the legal authority to do indirect source review. Therefore, the regional offices, already overburdened with work, would have to handle many ISR programs for the states.

Although there were many unresolved issues, the October 15 deadline forced EPA to promulgate the proposed ISR regulations as quickly as possible. On October 12 the proposed regulations were sent to the Office of Management

and Budget (OMB) for the required interagency review, and EPA requested that OMB respond within 24 hours. Normally the interagency review process is scheduled for a five week period. On October 15 EPA again asked OMB to respond quickly. On October 18 NRDC informed EPA that if the regulations were not issued by October 23 they would prepare a motion for contempt citation.¹⁹ Two days after NRDC filed a contempt motion in a federal court against two EPA officials and two OMB officials, the Administrator of EPA signed the regulations. The regulations were published in the Federal Register on October 30.²⁰

These regulations, which would take effect in any state that did not have an approved program, required that, prior to the construction or modification of any qualifying indirect source, an application providing air quality background data must be submitted and EPA must determine that the source would not violate the CO standard or hinder a state from attaining the CO standard at that location. The criteria for determining whether a source would be subject to ISR depended on whether the parking lot was within a designated area of high CO background levels. In a designated area, review was required if a new parking lot had spaces for 1000 or more cars, or would induce additional vehicle trips of 1000 or more in one hour, or 5000 or more in eight hours. In non-designated areas these figures were doubled.

At the time of promulgation of the proposed regulations, EPA had not completed many of the technical studies needed to justify its regulations and needed for the development of a model and guidelines for review of indirect sources. A number of critics of the proposed regulations argued that ISR would not correct any significant air quality problem. EPA's air laboratories and several outside consultants had begun a number of studies to demonstrate the need for and effect of ISR, and when the results of these studies were available in the winter and spring of 1974, EPA claimed that its ISR program was justified. Many people outside the Agency, however, remained skeptical and critical.

The major purpose of technical studies performed in late 1973 and early 1974 was not, however, to justify EPA's programs. EPA needed data for the development of a model to predict when an indirect source would cause a violation of the CO standards. Again, because of the uncertainty involved in monitoring and modeling techniques and because the technical basis for EPA's decisions was not readily available to interested persons as the regulations and review guidelines were being developed, industry and some EPA employees refused to endorse the ISR program.

After promulgation of the proposed regulations in October 1973, EPA needed time to evaluate the written

comments that were submitted. Moreover, because the regulations were to become law in states that had not developed their own ISR program, EPA was required to hold public hearings in such states. Notice of the public hearings was given on November 23, 1973,²¹ and the hearings were held by the regional offices in December. The deadline for final regulations was December 15, 1973, but early that month EPA asked for and was granted by the court, without objection from NRDC, an extension until January 31, 1974 for promulgation of the final regulations.

During the time that final regulations were being developed, EPA met with industrial representatives; received many comments on the proposed regulations from industry, the public, states, and other federal agencies; and held public hearings in over 40 states. The working group process was used for the final regulations, and on January 23 the EPA Steering Committee, made up of representatives of the top officials within EPA, met to review the regulations. A number of issues were still unresolved, and objections to the draft resulted in a memorandum on January 25 from the Office of Air and Water Programs to the Administrator recommending that EPA again request that the deadline be extended. This time NRDC objected to another long delay and the court gave EPA until February 15.

The regulations were redrafted in early February and submitted to the Administrator on February 12. CME had received earlier drafts of the regulations in January and received the final draft on February 13. On the next day the Administrator signed the regulations, and NRDC and a number of industrial groups filed suits in federal courts to review the regulations. During February and March more than fifty suits challenging the regulations were filed in courts around the nation. Because NRDC had filed quickly in the D.C. Circuit Court of Appeals and because that court had heard the earlier suit by NRDC, all suits were later consolidated in the D.C. Court.²²

These ISR regulations, labelled "interim final," were accompanied by an extensive preamble that discussed the comments EPA had received, explained the intent of the ISR regulations and the changes that were made, and asked for additional comments by April 1, 1974. The regulations stated that between February 1974 and July 1, 1974, the date the regulations would become effective, EPA would evaluate comments and, if necessary, again revise the regulations.

Changes made in the regulations included removing the "trip inducement" basis for review, leaving only the number of spaces for cars as the factor that would create a requirement for review. EPA cited a bill in Congress as "firm Congressional guidance" that the date when ISR would apply to new construction should be delayed from July 1,

1974 to January 1, 1975. The bill passed but was vetoed by the President.²³ A subsequent bill, with a similar six-month delay provision was later enacted.²⁴ July 1, 1974, however, remained the date when states and regional offices were to begin review of applications for sources that would commence construction after January 1, 1975.

With the effective date remaining July 1, the pressure remained on EPA to finish the guidelines and model for evaluating indirect sources. A February, 1974 status report on the guidelines set April 1 as the date for the draft and May 1 as the date for final revision. The draft guidelines, however, were not completed until May 1 and were only then submitted for review to those agencies and outside groups that had been working with EPA. By July 1, 1974 comments had been received and the guidelines revised. There had been some discussion of publishing the guidelines in the Federal Register to solicit public comments;²⁵ however, EPA chose instead only to give notice of their availability.

The guidelines set out a procedure for review of indirect sources. However, the background data and methodology necessary to permit users of the guidelines to evaluate the model was not included. For example, the meteorological sampling information was not available from EPA until after January, 1975. As a result many states and industries criticized the guidelines, claiming that they were neither necessary nor effective. Even EPA regional offices were unable to obtain the back-up material and were not convinced that the guidelines would work.

As had been suggested in the February interim final regulations, EPA also revised the ISR regulations at this time. A large number of comments had been filed in the spring of 1974, and EPA had met with industrial organizations and government officials to solicit comments and explain the ISR program. Although strong criticism of the ISR regulations continued, the amendments to the regulations were merely clarifications of the earlier provisions.

Thus the stage was set for states and regional offices to begin review of applications for permits to construct new sources. Starting on January 1, 1975, no new construction of indirect sources larger than the cut-off size was to begin without a permit from EPA or from a state which had an approved ISR program. Several applications for review would be submitted to regional offices, and, pursuant to a request from EPA's Administrator, the regional offices would hold hearings and workshops to explain and gain support for ISR. States and regional offices, however, were not enthusiastic about their new responsibilities, and the industries that would be regulated continued to carry their objections to the courts and the public. The general public began to view

the EPA programs as further hindrances to the use of automobiles, and, most importantly, opposition in Congress to all of EPA's parking programs was strong and growing.

B. The Suspension of Indirect Source Review Regulations

During the fall of 1974, EPA recognized that implementing the ISR programs in over 40 states that did not have their own programs would be an immense administrative burden on the regional offices. Officials in EPA and OMB also expressed the view that the federal government should not try to run a facility-siting review program. Such programs should be part of the planning processes of local governments. In fact, in the fall of 1974, only EPA's Air Programs Office appeared ready and willing to implement the indirect source review program. They have, however, never had the chance to do so, and it is possible that they never will.

With the January 1, 1975 date of application only months away, OMB was arguing against the initiation of the program, and developers and retailers were asking the court to enjoin the program. Congress, however, took the decisive steps. Congress had briefly considered the issue of ISR in the beginning of 1974 and had directed EPA to delay the programs until January 1, 1975.²⁶ In the fall of 1974 Congressional committees with jurisdiction over the Clean Air Act, however, were not ready to seek further changes in this law, for to do so would open the Act to other amendments. Therefore, opponents of ISR took the fight to the appropriations committee of the House where the chairman, Representative Whitten of Mississippi, was sympathetic to their position. Representative Casey of Houston proposed an amendment to EPA's appropriation bill, prohibiting EPA from spending any funds to implement indirect source review.²⁷ The bill passed two weeks before ISR was to become applicable, and EPA found it necessary to reconsider what could be done with the ISR program. At the same time, motions for stay in the Court of Appeals were forcing EPA to explain its position on ISR to the court.

After consulting with interested parties, EPA laid out its options. Most of the people who had worked on the development of ISR regulations were reluctant to have the program killed. They believed that EPA should continue to support its past positions and express confidence in ISR as a tool for air quality control. Some EPA personnel and outsiders wanted EPA to interpret the appropriations bill in a manner that would allow the program to continue. Because the language of the Act only restricted the regulation of parking facilities, the previously considered option of reviewing indirect sources on a trip inducement basis rather

than on the capacity of parking facilities seemed possible. A Congressional aide suggested that because the January 1, 1975 date for ISR was set both by Congress and the courts and because the money was now cut off for review, no new construction in the U.S. could begin until EPA again had the power to approve construction. The more realistic options, in light of clear legislative history, however, were to delay the ISR regulations or to revoke them.

Option papers and interpretation of the legislation were circulated, and the consensus of opinion was that EPA should delay the effective date until the end of the appropriations limitation on July 1, 1975. That would mean that EPA would begin reviewing ISR applications after July 1, 1975. Setting the date when ISR would apply to construction was more difficult. This date would be the "grandfather" date after which no new construction could begin without EPA approval. It was assumed that this date would have to be set after July 1, 1975 to allow time to process the applications; however, EPA was reluctant to delay the ISR program longer than necessary. On December 23, when Russell Train signed the order to suspend ISR, EPA informed the D.C. Court of Appeals only that the effective date would be July 1, 1975.

Prior to EPA's announcement, there had been an internal fight over the "grandfather" date. October 1, 1975 appeared to be the earliest date for getting the program started, but the EPA Administrator believed that a six-month grace period was needed between effective and "grandfather" dates. His decision, however, was reconsidered when a Congressional aide objected. To set a "grandfather" date as January 1, 1976 would appear to be bowing to the pressures of the appropriations bill and thus to Representative Whitten and the appropriations committee. The staff members of the Congressional committees having jurisdiction over EPA's statutory authority wanted the appropriations committee to be given no more recognition than necessary. EPA was asked not to refer to the appropriations bill as the cause of its decision to delay in its Federal Register notice. Therefore EPA's public announcement of suspension referred to the public debate and misunderstanding as the basis for its decision and set no "grandfather" date.²⁸

EPA also announced in the Federal Register notice that a fully approved SIP should continue to include an ISR program and that the suspension of the federal program did not apply to state developed regulations. Representative Casey objected to the interpretation that EPA could continue to approve state SIPs with ISR programs, encourage states to develop ISR regulations, and allow states to use EPA grants for ISR. He believed that such an interpretation would require the Agency to spend funds in violation of the appropriations bill. Many companies and organizations also

objected to EPA's position. Casey asked the General Accounting Office (GAO) to examine EPA's interpretation in January 1975, and, upon doing so, GAO did not disagree with EPA.

EPA, however, still had to face the "grandfather" date issue. The Court of Appeals had told EPA to report on the action it expected to take under the appropriations bill. On January 27, 1975 EPA responded that it would delay the "grandfather" date until January 1, 1976. After EPA announced this publicly on March 7, 1975, NRDC filed a motion to compel EPA to change the "grandfather" date to July 1, 1975. The court, however, dismissed NRDC's motion.

In early February, EPA drafted a set of revisions to the ISR regulations. The "grandfather" date would officially be changed to January 1, 1976. When an action memorandum for these revisions was circulated to the Steering Committee in early March, EPA's General Counsel pointed out that, if the regulations were issued, EPA would appear to be "champing at the bit" to get ISR going again.²⁹ Congress might be provoked to further action. As a result, these regulations were not promulgated.

In May, 1975, EPA held a number of meetings to discuss the options available to it. More than two years had elapsed since the original NRDC lawsuit had laid the groundwork for the development of ISR. Congress was again considering amending EPA's appropriation bill to prohibit the agency from using funds to regulate parking lots.³⁰ The options available to EPA had not changed since December, 1974. The Agency could wait to begin its ISR program until the new appropriations bill took effect and then try to get around the language of the bill. EPA could revoke the program entirely and bow to the general Congressional directive. EPA could again suspend the regulations for a year until it regained the necessary authority. Finally, EPA could suspend the program indefinitely and wait for specific guidance from Congress when it amended the Clean Air Act. The last option was favored, and in June, 1975 EPA announced it was considering indefinite suspension.³¹ The regulation providing the indefinite suspension was signed on June 26 and was published on July 3.³²

Again EPA announced that ISR should be a part of all state SIP's, and Regional Administrators were told to encourage states to develop ISR regulations. Again Representative Casey wrote to EPA questioning this interpretation. EPA responded that its position was that, under the law and the court order, it must require that SIPs provide for attaining and maintaining the air quality standards. However, EPA would abide by the intent of the appropriation bills and not promulgate or implement federal

ISR programs for states that did not develop their own ISR programs.

In the current amendments to the Clean Air Act, Congress is facing the issue of ISR. It appears that authority for ISR programs will be delayed for several years. Some Congressmen are pushing for language that allows ISR to be reinstated only if EPA makes a showing that the program is feasible and necessary. Others want ISR to be left entirely to the states. In any case, EPA is not likely to reinstate ISR soon even if the Agency is fully satisfied it can show a great need. The indefinite suspension is actually a revocation, because EPA has told the court that the entire ISR program would be put through the rulemaking process again before being reinstated.

II. MAJOR ISSUES FOR INDIRECT SOURCE REVIEW

Within the process of developing ISR regulations, EPA was faced with a number of decisions on which the success or failure of the ISR depended. For example, central to the review for indirect sources was a model for predicting the impact of an indirect source on ambient levels of CO. Such a model had to be capable of withstanding the inevitable challenges from effected industries that it was neither accurate nor relevant to air quality problems. At the same time, the model had to be simple enough to be used without great expense by states, regional offices, and the industry. Such a litmus test, however, was not easily developed, and the lack of acceptance of EPA's models seriously eroded support for the ISR program.

This part of the case study will examine the development of the scientific and technical basis for ISR, and the development of information on the economic impact. In addition, the problems of implementing ISR will be discussed briefly. These three sections illustrate in more detail the types of problems EPA faced in developing ISR regulations.

A. Scientific and Technical Issues

The success of ISR programs depended upon the formulation of models to predict where ISR would be needed and what effect ISR could have on CO emissions and on ambient air quality. However, because EPA had delayed its programs for control of traffic-related pollution in 1970 and 1971, the Agency was not in a good position to gather and analyze the necessary scientific data on which to base ISR regulations within the deadlines.

1. Size Cut-Off for Application of ISR

One of the first issues that EPA had to resolve in developing ISR regulations involved the criteria that would be used to initiate the review process for any source. The administrative burden of reviewing all new construction and modifications of facilities with parking lots would be too large to handle. EPA assumed that some criteria could be established to predict a probable violation of the air quality standards for CO and thus indicate the need to analyze the CO impact in greater depth.

In March, 1973 EPA's Air Monitoring and Data Analysis Branch was asked to examine the possibility of using size as the determining criteria. The Branch made estimates of the traffic flow and air quality impact for various types of sources, such as shopping centers, where a continuous or constant flow pattern could be expected, and sports complexes, where there would be periods of peak traffic flow and periods of no traffic. Given one- and eight-hour average ambient air quality standards for CO, and assuming low CO background levels, EPA estimated that lots smaller than 1,000,000 square yards for shopping centers and 100,000 square yards for sports complexes would not require review.³³

In July, 1973 the EPA's Air Standards Implementation Branch sent a memorandum to the regional offices, CGC, and other air program offices presenting a recalculation of size criteria. Again simplifying assumptions and a lack of validating data resulted in very rough estimates. This time the size criteria for both types of sources were established as 24,200 square yards, the size needed for 675 car spaces.³⁴ Shortly thereafter, however, the desirability of relying on parking lot size as the criterion for review was challenged. Employees at EPA's Region VIII commented that some sources had small lots or no lots, but still could seriously affect CO levels.³⁵ "Drive thru" facilities or small lots in areas of high CO levels could cause violation of the CO standards. Concern was expressed that if a size criterion such as 1000 vehicle spaces was chosen, sources would construct lots with 999 spaces. One regional office recommended a less specific size cut-off and the addition of vehicle attraction criteria so that any facility that drew a large number of vehicles to its site could be regulated.

In the ISR regulations proposed in October, EPA established two criteria for review of new construction. Any source with 1000 or more spaces for cars or any source that attracted either 1000 or more cars in one hour or 5000 or more cars in eight hours would be subject to ISR regulations.³⁶ EPA's prior estimates of size criteria influenced these figures, but the administrative burden that would result from too low a cut-off number was also a major

factor in the decision. Estimates of future construction in the United States from the International Council of Shopping Centers showed that if a 1000 car lot was set as the lower limit for ISR, about 500 sources would need to be reviewed per year.

Several comments on the proposed ISR regulations criticized EPA's selection of the 1000 car cut-off as too large. The National Realty Committee (NRC) had begun to examine the relationship of size to CO levels and believed that a 250 car lot was a more appropriate cut-off size. (NRC represents large developers and admits that it preferred to have small developers included under ISR regulations both for purposes of competition and to force EPA to set up an expedited review process for the thousands of applications it would receive with the smaller cut-off size.) The NRDC commented that CO background levels should also be evaluated and smaller lots should be reviewed when they were apt to produce violations because of high background levels. (EPA later developed parking management programs that required a similar type of review process for lots of 250 or more cars in those areas where it was likely that CO background levels would be a significant problem.) The trip inducement criteria were also criticized as unworkable.

In the final regulations, the 1000 car lot size was retained as the cut-off figure. EPA argued that the impact of smaller sources did not justify the detrimental diversion of manpower that would result from increased numbers of applications.³⁷ EPA dropped the trip inducement approach, stating that predictions of the trip inducement would be too hard to make and that major enforcement problems would result. EPA argued that it would be very difficult to penalize a developer if an application predicted induced flow below a criterion or low enough that a detailed review estimated that no violation would occur and later the actual induced traffic flow caused violations in the ambient standards.

While EPA first approached the problem of determining the criteria as a technical issue, the administrative and political constraints quickly became important. The decision to establish the cut-off size at 1000 cars was thus a compromise between the low figures suggested by air quality and the higher figures suggested by the cost of review.

2. Development of Review Guidelines

The major technical problem facing EPA was the development of a model to predict whether an indirect source larger than the size criteria would actually cause a

violation in the ambient air quality standard for CO. Such a model would have to be reduced to a set of simple guidelines explaining how to determine traffic flow patterns, background CO concentrations, and resulting ambient CO levels at any indirect source. The accuracy of the model, however, could not be sacrificed for the sake of simplicity. Ned Meyer of EPA, who was the principal developer of the model used in the guidelines, viewed the compromise between simplicity and validity as his most difficult problem.

The approach used by EPA to build the model consisted of: (1) developing predictions of traffic flow patterns around indirect sources, (2) relating traffic flow to emission levels, and (3) relating emission levels to ambient quality.

To get a general idea of the CO problems around indirect sources, EPA did two studies of shopping centers in March, 1973 in Raleigh, North Carolina.³⁸ EPA found no violations of the one hour standard of 35 ppm but did find some violations in the eight hour average standard of 9 ppm if eight one hour samples were averaged. By June, 1973, EPA had prepared a document summarizing the current knowledge and techniques available for ISR.³⁹

EPA planned to develop a screening technique that called for the measurement of background levels at the site and the use of an indicator of CO contribution based on size. The screening technique would indicate whether detailed analysis of air quality impact would be needed. At this time, however, EPA recognized that better data to refine and validate the Agency's models were needed.

In the spring of 1973 EPA contracted with Geomet for seven studies of traffic flow patterns around different types of indirect sources. These studies would give EPA data on the speed of vehicles and the average length of time a vehicle was running in and around a parking lot. The results were available in the fall of 1973 and indicated that traffic flow could not be predicted with much accuracy during congested periods when the CO levels were likely to be greatest.⁴⁰

In the summer of 1973, EPA performed an additional study of CO levels at an indirect source. This study examined an event-oriented type facility, a sports complex, and revealed that ambient levels of 50 to 60 ppm were not unusual for short periods of high congestion and that traffic control near the exits and entrances was the key problem.⁴¹

For a method to relate traffic flow data, such as vehicle speed and idling time, to CO emissions, EPA called upon its Ann Arbor laboratory. The laboratory had worked on

determining the average mix of vehicles across the nation. Using this average vehicle mix and emission data, the average emissions per vehicle at any given speed could be estimated. Thus, EPA could relate traffic flow at a source to expected emissions. However, using the national mix and the average emissions levels did not allow EPA to consider the local mix of vehicles or how temperature would affect emissions. The problem of increased emissions during a cold start was raised in several comments, and NRDC informed EPA of several relevant studies.⁴² (The rich fuel mixture needed to start a cold car engine causes increased CO emissions.) One of the studies had, in fact, been done by EPA's Ann Arbor laboratory. EPA later worked temperature variations and cold-start problems into its model.

The last step of relating emission levels to ambient levels was done by EPA with the "roll back" techniques that had been employed for other types of air pollution models. Empirical data was needed to test this technique, and in December, 1973 EPA contracted for a study of CO levels and traffic patterns at a shopping center during the Christmas rush.⁴³ This study verified that violations of CO standards would occur at such shopping centers and indicated that the roll back model could be used. EPA was, however, not satisfied that there had been adequate validation of its models and contracted with the Stanford Research Institute (SRI) to do more extensive validation studies.

While EPA was developing its methodology, the California Business Property Association (CBPA) contracted with SRI for a model to analyze the CO impact. The model was made available to EPA and proved useful. EPA, however, was not in a position to use the model directly since SRI's model was proprietary information and, therefore, developers would have to pay to use it. EPA needed to develop a model that anyone could use freely.

Another study was done by A.D. Little for J.C. Penney. It examined the CO levels around parking lots to give J.C. Penney an independent look at the problem. The study, however, examined average CO levels over a parking lot rather than at any specific point, and the methods used for monitoring made it impossible to relate the data to EPA's model. J.C. Penney believed that the study showed that public exposure to high CO concentrations was not a significant problem. The company also reiterated a comment by CBPA that people would not remain at a fixed point in a lot for one hour. CBPA suggested that exposure levels for an average person moving through and around a lot be worked into the model. However, EPA labeled this comment a red herring and argued that the law requires that there be no violations of the one hour air quality standard which is designed to be a control on ambient levels of air quality

regardless of the exposure or dosage levels to an average person.

From the data gathered, EPA refined the model and drafted guidelines in the spring of 1974. In April, 1974 it submitted a draft to interested parties. EPA received extensive comments and is especially commendatory about the help it received from NRDC and SRI. In May, 1974 EPA sponsored a seminar on the guidelines for regional personnel and employees of other federal agencies. In July, 1974, at the time the review process began, a draft version of the guidelines was published.

The draft version of the guidelines, however, did not include scientific support documents such as the meteorological assumptions. Both the regional offices and states complained that the guidelines could not be evaluated or understood without the supporting data. The final guidelines were not published until after December, 1974, when the first suspension decision had been made.**

While regional offices and states complained of the difficulty of using the guidelines and of explaining their relevance and basis to affected industries, industrial groups challenged EPA in court for failing to provide an opportunity for them to evaluate and comment on the scientific data and models. Predictably, when the guidelines were issued, they met with widespread criticism and little effort was made to implement the program.

B. Economic Impacts

The development of economic information may have been the most harmful aspect of EPA's decision-making process for ISR. Although EPA rushed to gather information on the technical and scientific bases for ISR programs, the Agency was slow to evaluate the costs of ISR and the impact of ISR on growth and development in municipalities. Moreover, EPA completely failed to examine the benefits of ISR, such as reduced exposure to CO and, therefore, could only argue that the economic disruptions were being minimized and that the costs to industry would not be significant.

Even when EPA tried to develop economic information on which to argue its case, the Agency failed to stem the criticism. During the development of the proposed and interim final regulations, EPA had received a number of comments about the economic and social impact of ISR. However, it wasn't until after the interim final regulations were promulgated that EPA's Office of Planning and Evaluation (OPE) initiated detailed studies needed to respond to these comments. The studies failed to resolve the issues of how ISR would affect the regulated industries,

state and local governments, and the public, and, instead, added information which was used to support the positions of those critical of EPA's program.

1. Opposing Views on the Economic Impacts

During the early development of ISR regulations, developers, realtors, and retail organizations were primarily concerned that ISR would greatly increase costs and would delay or foreclose much of the new development. The National Association of Realtors, for example, testified before a Senate committee that:

It has become much more difficult for the small developer to compete. Many have gone out of business. Competition has been reduced. Overall productivity has suffered. Why? When faced with environmental litigation, indirect source regulations, transportation control plans, severe hookup restrictions, water discharge permits, land use controls, emission controls, wetland protection, open space regulations, and the like, many developers and investors throw up their hands in despair.⁴⁵

Developers complained about the costs of the review process, such as costs of uncertainty associated with whether a permit would be granted and costs resulting from delay of construction while the development plans were being evaluated. These costs can be significant because they threaten to increase the "front end" expenses that are paid out of developers own funds and tend to retard the quick recovery of such funds that are needed to "seed" other projects.⁴⁶

State and local governments were also concerned with costs resulting from ISR programs; reviewing agencies would be faced with large administrative and financial burdens. States argued that EPA would need to supply more funds or require that applicants be responsible for providing the analyses of the air quality impact.

Land use and development issues were also raised by opponents to ISR. Industrial representatives argued that the size cut-off of 1000 cars within a designated area and 2000 everywhere else would lead to smaller and more dispersed facilities and thus "urban sprawl."⁴⁷ A study commissioned by the National Realty Committee pointed to several factors that would create sprawl. Developers would attempt to avoid the review requirements for air quality by building smaller facilities or by locating developments in areas with low background concentrations of pollutants. In addition, ISR would prohibit the siting of major

developments in or near cities where violations of the standards existed.⁴⁸

State and local governments were concerned about the effects of ISR as a land-use control technique based solely on considerations of air quality. They argued that land-use patterns should be determined through a balanced view of many environmental, economic, and social factors. ISR was especially objectionable to the state and local governments because it appeared likely that the federal government would be implementing these land-use controls.

EPA did not believe that the ISR program would have an adverse impact on development or urban growth. "[T]he purpose of these regulations is not to preclude development except in those rare cases in which no accommodation with air quality maintenance can be reached."⁴⁹ Indirect source review was primarily designed to insure maintenance of air quality standards, and EPA believed that most indirect sources could be built, assuming they incorporated a good design for smooth traffic flow. EPA did, however, agree that under its regulations construction of large indirect sources could be forbidden at certain sites. EPA also stated that not many sources would be affected and estimated that only 350 shopping centers per year and an additional 150 parking lots and garages would be subject to review.⁵⁰

EPA argued that the economic impact of ISR was not so large that developers would build smaller sources and increase urban sprawl:

As long as there are economic incentives favoring development of large projects, the Administrator does not believe that developers of larger projects will change their scope of operations solely for fear of indirect source review.⁵¹

Finally, EPA suggested that delay and uncertainty costs would not be great:

Developers will be encouraged to apply for review under these regulations as early in the development process as the information required can be prepared. Thus, applicants will be able to ascertain whether their plans will be acceptable under the regulations well before substantial sums are expended in relation to total project cost.⁵²

2. The Harbridge House Report

When the interim final regulations were published, EPA was only able to make general arguments about the economic impact. No formal analysis of the economic impacts of ISR

had been done. EPA's OPE urged that this vacuum be filled and commissioned studies in March, 1974 to examine the economic and land-use impacts and to determine how ISR could be incorporated into development plans.

OPE let two contracts: one with Peat, Marwick, Mitchell, and Company and the other with Harbridge House. The former was for a study of the long-term impacts of ISR on land-use and air quality. The effect of transportation control measures and ISR on air quality maintenance in San Diego was to be examined. EPA, however, found the final report unsatisfactory because the contractor had not evaluated the land-use impacts associated with large parking lots or with highly congested areas.

The Harbridge House study, The Economic and Land-Use Impact of Federal Regulations to Review New Indirect Sources of Air Pollution Prior to Construction (October, 1974), was designed by OPE for three purposes:

Assessment of the magnitude and incidence of costs of the indirect source regulation to the developer related to possible design changes necessitated by review requirements, possible time delays, and any additional data demands generated by the review process.

Determination of the impact of indirect source review requirements on developer location and facility design decisions with an assessment of the probable impact of these decisions on land-use development patterns and area-wide patterns of vehicle miles traveled.

Identification of problem areas in administering the regulations and suggestions in the form of guidelines to eliminate or ameliorate the problems.⁵³

For its data, Harbridge House relied on a literature search, case studies of costs associated with meeting review requirements of six existing facilities (two shopping centers, two office space facilities, and two mixed use projects), and the limited experiences of state developed ISR regulations in Florida, Oregon, and Pennsylvania. The data were, in almost all cases, supplied by industries.⁵⁴

The study designated three types of costs: costs of data acquisition and ISR application preparation, costs of delay (e.g., inflation while waiting for the permit), and costs of design change needed for compliance with air quality standards. Several key assumptions were made in evaluating these costs: inflation would be 1 percent per month (12 percent annually); data costs included computer

modelling; interest rates were held constant; and the developer, not the public, would bear all design change costs including highway and transit design changes.

The conclusions of the report dealing with the economic impact on development are summarized in Table 2. Costs associated with data acquisition were generally less than one tenth of one percent of project costs. The report suggested that delay costs would be greatest for the first two to five years, and then drop dramatically because projects already planned would have more difficulty integrating ISR requirements. Ninety day delay costs range from 3.5 to 7.5 percent of front end investments. Design change costs are the largest, particularly for shopping centers.

Of the types of facilities examined, shopping centers appear to be the most seriously effected; there is little appreciable impact on office parks or mixed use developments. One of the shopping centers (Project F) requires an eight percent rent increase to make the project feasible. The design change costs on Project B render it unfeasible; however, project B is a special case, since it was a marginal development in the first place (only a 14 percent rate of return before ISR). Moreover, because it is located in a highly congested area, the problem of violations of air standards becomes much more difficult.

With regard to the land-use impact of ISR, Harbridge House summarized its findings as follows:

The study analysis indicates that the impact of ISR on location will generally be to reinforce existing trends of suburbanization. In the case of shopping centers, it was found that ISR and its attendant costs may provide developers with a marginal incentive to locate in suburban areas where air quality is relatively good and ISR-related costs would be minimized. The effect of ISR on suburbanization of office buildings was found to be small compared to the effects of the state of the economy and the availability of financing and labor. Short of denial of a permit for construction, ISR was found to have no effect on the location of mixed-use developments.⁵⁵

Once the report was made available to the public, EPA received many critical comments. Developers argued that the 12 percent annual inflation rate was too low and that Harbridge House had underestimated costs due to delay. Despite the criticism, however, developers were eager to use some of the results of the report to support their position.

TABLE 2
SUMMARY OF SIX CASE STUDY ANALYSES*

	TOTAL COSTS			RETURN ON INVESTMENT		
	WITHOUT ISR	WITH ISR No Delay	WITH ISR 90 Day Delay ^a	WITHOUT ISR	WITH ISR No Delay	WITH ISR 90 Day Delay ^a
Office Park						
Project A	\$31,425,000	\$31,428,215	\$31,749,222	19.1%	19.1%	18.6%
Project E	24,800,000	25,202,080(H) ^b 24,977,480(T)	25,301,601(H) 25,079,001(T)	21.0%	20.2%(H) 20.3%(T)	20.0%(H) 20.1%(T)
Shopping Center						
Project B	37,200,000	38,892,000	39,811,300	14.2%	12.2%	11.3%
Project F	13,712,000	16,480,750	16,824,121	30.3%	20.2% 24.6% ^c	19.2% 23.5% ^c
Mixed Use						
Project C	27,750,000	27,753,000	28,221,757	12.8%	12.8%	12.1%
Project D	113,982,000	115,613,300	116,464,700	(3.9%)	(4.2%)	(4.4%)

^a Inflation rate of 1 percent per month

^b H = Highway Design Change

^c T = Transit Design Change

With an 8 percent increase in rents

*SOURCE: Harbridge House, Inc., "The Economic And Land Use Impact of Federal Regulations To Review New Indirect Sources of Air Pollution Prior to Construction," Report to EPA, October, 1974, p. I-4.

Reaction at EPA varied. The project officer in OPE seemed generally satisfied with the report. The air office, on the other hand, was concerned about the costs Harbridge House cited, largely because the report was used by developers in their testimony before Congress on EPA's program. The air office prepared a summary and analysis of the report, which tried to show that the assumptions used by Harbridge House were biased in favor of higher costs.⁵⁶ For example, EPA argued that only current developments would require design changes. In the future developers would incorporate air quality impact information into their development process, thereby reducing the need for, and hence the cost of, most design changes. In addition, the air office feared that because the report relied on developers for its data, the cases were biased.

Although the report was not completed in time to affect EPA's final ISR regulations, it did play a role in the public debate and Congressional action that led to the suspension decisions. A draft report, which lacked analysis and was viewed by EPA as unsatisfactory, was released when EPA's appropriations were being considered by Congress. Developers seized the report as an EPA document that indicated ISR costs would be excessive. EPA countered by arguing that developers were pulling statements out of context, but the net effect of the report was to reduce support for ISR in Congress. More recently critics of ISR have relied on the report in testimony before Congress on amendments to the Clean Air Act.

C. Problems of Implementation

Immediately after EPA began to consider a program for review of indirect sources, problems of implementing the program became obvious. ISR is, to a large extent, a tool for land-use control and questions were raised concerning whether EPA or the states had authority to control motor vehicle emissions with such a program. Even if the states possessed adequate authority, EPA doubted that they would be eager to develop their own ISR programs. EPA, however, had to ensure that ISR was implemented by a qualified local, state, or federal agency.

Although EPA's authority to enforce an ISR program has been challenged several times, it appears that the Clean Air Act provides the necessary authority. Under the Act, EPA is directed to require state implementation plans to include "emission limitation, schedules, and timetables...and such other measures as may be necessary to ensure attainment and maintenance of standards, including, but not limited to land use and transportation controls."⁵⁷ EPA's General Counsel has argued that EPA has the authority for ISR,⁵⁸ and several

courts have upheld other EPA programs involving land-use controls for vehicle-related pollution.⁵⁹

Once EPA was satisfied that it had the authority to implement ISR, it had to face the question of whether it had the resources to administer the program. Most of EPA's regional offices are already overburdened and the regional offices prefer to rely on state agencies whenever possible. In 1973 EPA surveyed the laws and regulations of states and determined that many states did not have adequate authority to carry out ISR.⁶⁰ Moreover, the states were also short of resources, and EPA was not surprised when only about a dozen of the states took serious steps to develop their own ISR regulations.

Concerned about the implementation problems, EPA considered several alternatives. The Air Programs Office suggested that EPA could require states to administer ISR regulations by requiring sources to get permits and providing that only states, and not EPA, could issue permits. Forcing the states to administer an effective permit program, however, might require the use of sanctions against the states, and EPA was not confident it had the authority to actually force the states to act.⁶¹

A second option consisted of delegating federal ISR authority to an agency of a state or local government, instead of requiring the agency to develop its own program. Therefore, agencies without the necessary authority to develop their own program could become agents of the federal government for the implementation of ISR. In the February 1974 interim final regulations, EPA provided for such delegation of federal authority to state and local agencies.

By opening up the possibility of delegation, EPA had to face a number of delicate issues. Under a principal-agency relationship, would EPA have to review and be responsible for its agent's actions? What would happen if more than one governmental body or agency sought the authority to review the same area? What legal authority must an agency possess before EPA could delegate ISR to it? Most of the issues involved in this delegation approach remain unresolved. In the fall of 1974, EPA struggled with the issues on a case by case approach. Only the State of Kansas, the City of Dallas, and a few other government bodies made any effort to receive delegation. The legal uncertainties and political pressures caused delegation decisions to be delayed, and the suspension of ISR regulations has now ended the need to resolve the issue for ISR programs. If ISR is ever reinstated, implementation may prove to be far more difficult than any of the previous problems faced by EPA.

III. CONCLUSION

As clearly as the origins of indirect source review programs can be traced to a federal court decision, the termination can be linked to the actions of Congress. However, the forces that actually caused the suspension of EPA's program are not so obvious.

Certainly, EPA must accept some of the responsibility. EPA avoided dealing with the problems of vehicle emissions until the court forced it to act. By then, the Agency had lost some of the time needed to develop controls on traffic flow. Once EPA began to address solutions, it failed to develop a plan for ensuring that the technical and economic information to support and justify ISR would be available as needed. Finally, EPA never analyzed and solved the vast problem of how to implement its program. During the six month period before the initial suspension, EPA had an opportunity to begin the permit program for ISR; however, the regional offices lacked the necessary resources and information, and EPA had failed to resolve the conflicts that inhibited states from accepting the burden of administering ISR.

Total blame, however, can not be placed on EPA. The nature of the problems and the timing of the solutions may have sentenced a program like ISR to failure regardless of how EPA performed its responsibilities. ISR was developed to solve one small part of the problem of motor vehicle emissions. The problem of the build up of pollutants at local hot spots was not obvious nor was it an issue that would generate public sentiment for a quick and dramatic corrective action. In addition, local governments were never likely to support a program that preempted some of their authority to make major decisions about local development.

Although EPA undertook a major effort to educate and involve interested parties, ISR remains an unknown commodity with uncertain benefits. Representatives of EPA, the National Realty Committee, and the Natural Resources Defense Council can reiterate their belief that implementation of ISR would be beneficial and workable, but the program will never attract strong supporters.

Another major impediment to the ISR program involved the fact that it was not linked to the requirements of direct vehicle emission controls. Emission controls on automobiles can add little to the abatement of air pollution until a significant number of cars have been manufactured with such controls. In addition, the requirements of direct controls on automobiles have been continually delayed by EPA and Congress. As a result, rapid implementation of indirect controls on automobile pollution, such as ISR, must have

seemed unwarranted to many. Moreover, ISR programs were linked to the transportation control plans that have outraged large segments of the public in many major cities.

Perhaps EPA's experience with ISR has produced an awareness within the Agency of the importance of developing a constituency that will actively support the Agency's actions. A more optimistic observer would credit ISR programs with teaching developers, local governments, and Congress about the importance of recognizing the interrelationship between automobiles, use of land, and pollution. This can be a very important lesson to a society dependent upon automobiles.

NOTES

- 1 The author would like to thank Eric Smith for his valuable research assistance executed in his own refreshing and inimitable fashion.
- 2 Clean Air Amendments of 1970, 42 USC 1857c-4(a) (1970).
- 3 C.F.R. Vol. 40, Sec. 50.6 (1976).
- 4 C.F.R. Vol. 40, Part 52 (1976).
- 5 Clean Air Amendments of 1970, 42 USC 1857f (1970).
- 6 Federal Register, Vol. 39, p. 7270 (February 25, 1974).
- 7 C.F.R. Vol 40, Sec. 50.4 to 50.11 (1976).
- 8 C.F.R. Vol. 40, Part 51 (1976).
- 9 Federal Register, Vol. 37, p. 10842, 10845 (May 31, 1972). Delays are authorized by the Clean Air Act if the necessary technology is unavailable, 42 USC 1857c-5(e) (1970).
- 10 Federal Register, supra note 9.
- 11 Memorandum was prepared for the Interagency Task Force on State Air Pollution Implementation Plans.
- 12 Memorandum from Robert Baum, Associate General Counsel for Air Quality, to Robert Sansom, Assistant Administrator for Air and Water Programs, October 30, 1972.
- 13 Natural Resources Defense Council, Inc. v. Environmental Protection Agency, 475 F.2d 968 (D.C. Cir. 1973).
- 14 Ibid. A similar case emphasized the duty of EPA to promulgate transportation controls. City of Riverside v. Ruckelshaus, 4 ERC 1728 (C.D. Cal. 1972).

- 15 Federal Register, Vol. 38, p. 6279 and 6291 (1972).
- 16 EPA Action Memorandum dated March 2, 1973.
- 17 Ibid.
- 18 Memorandum from R.L. Borlick to John C. Court, March 29, 1973 states that EPA's "lack of knowledge concerning how to treat the problem precluded any action" prior to the court suit.
- 19 See, memorandum from Michael James to Alan Kirk, both of the Office of Enforcement and General Counsel, October 18, 1973.
- 20 Federal Register, Vol. 38, p. 29893 (October 30, 1973).
- 21 Federal Register, Vol. 38, p. 32286 (November 23, 1973).
- 22 The cases were dismissed on December 21, 1976, *Sears, Roebuck v. EPA*, 9 ERC 1751 (D.C. Cir. 1976).
- 23 Emergency Energy Act of 1974, (Senate Bill No. 2589).
- 24 Energy Supply and Environmental Coordination Act of 1974 (ESECA), PL 93-319. Passed June 24, 1974.
- 25 Ibid. ESECA had required all plans and regulations relating to ISR to be published for public comment. EPA first interpreted the requirement to mean the guidelines had to be published. They reversed their position in July, 1974, but later, in response to arguments in court, EPA agreed that before using them, the guidelines would go through the rule-making procedures.
- 26 Ibid.
- 27 Sec. 510 of the Agriculture, Environmental and Consumer Protection Appropriations Act of 1975 (P.L. 93-563) provided: "No part of any funds appropriated under this Act may be used by the EPA to administer any program to tax, limit, or otherwise regulate parking facilities."
- 28 Federal Register, Vol. 39, p. 45014 (December 30, 1974). EPA noted that "certain other questions relating to the regulations are being reviewed" and would be resolved within a few weeks.

- 29 Memorandum from EPA General Counsel to EPA Administrator, March 12, 1975.
- 30 Sec. 407 of the HR 8070. This Appropriations bill passed in October, 1975.
- 31 EPA Environment Reporter, Current Developments, p. 356, June 20, 1975.
- 32 Federal Register, Vol. 40, p. 28064 (July 3, 1975).
- 33 Memorandum from H.H. Slater, Chief, EPA Source Receptor Analysis Branch to John Fink, EPA, March, 1973.
- 34 Memorandum from Norman Edmisten, EPA, to Regional Offices, July 10, 1973.
- 35 Memorandum from Charles Murray, EPA Region VIII, to Norman Edmisten, EPA, July 24, 1973.
- 36 Federal Register, supra note 20.
- 37 Federal Register, Vol. 39, p. 25292, 25293 (July 9, 1974).
- 38 Memorandum from Ned Meyer, EPA, to Robert E. Neligan, EPA, April 23, 1973.
- 39 See Appendix O to the July 1973 regulations for SIPs. Federal Register, Vol. 38, p. 1583 (July 18, 1973).
- 40 Geomet, Inc. "Vehicle Behavior In and Around Complex Sources and Relate Complex Source Characteristics," 7 Volumes, Fall, 1973.
- 41 Memorandum from Edwin Meyer, EPA, to Jean Schueneman, EPA, August 31, 1973.
- 42 Letter from David Hawkins, Natural Resources Defense Council, to E.L. Meyer, EPA, December 4, 1974.
- 43 GCA Corporation, "Validation Study of an Approach for Evaluating the Impact of a Shopping Center on Ambient Carbon Monoxide Concentrations," EPA Contract #68-02-1376, 1974.
- 44 EPA, "Guideline for Air Quality Maintenance, Planning and Analysis, Volume 9: Evaluating Indirect Sources," January, 1975.

- 45 Testimony of Myron C. Roberts, Chairman of Realtors Legislative Committee, National Association of Realtors, before Subcommittee on Environmental Pollution, Senate Committee on Public Works, Oversight Hearings on the Clean Air Act, May 22, 1974.
- 46 National Realty Committee, Inc., "Comments on Proposed EPA Promulgation of Indirect Source Regulations for Inclusion in State Implementation Plans," November 29, 1973.
- 47 The environmental, economic, and social costs of urban sprawl are documented in a CEQ study, The Costs of Sprawl, April, 1974.
- 48 National Realty Committee, supra note 46.
- 49 Federal Register, Vol. 39, p. 7274 (February 25, 1974).
- 50 Briefing Materials for Administrator's Press Conference on Proposed Regulations for Review of Indirect Sources, October, 1973.
- 51 Federal Register, Vol. 39, p. 7272 (February 25, 1974).
- 52 Ibid., p. 7274.
- 53 Memorandum from Al Alm, Assistant Administrator of EPA's Office of Planning and Management, to Roger Strelow, Assistant Administrator of EPA's Office of Air and Waste Management, May 13, 1974.
- 54 Harbridge House is owned by Sears, Roebuck.
- 55 Harbridge House, "The Economic and Land Use Impact of Federal Regulations to Review New Indirect Sources of Air Pollution Prior to Construction," October, 1974 p. I-10.
- 56 EPA, "A Summary and Analysis of the Harbridge House Report on Indirect Source Regulations," p. 6, 1974.
- 57 The Clean Air Amendments of 1970, 42 USC 1857c-5(a) (2) (B) 1970.
- 58 Memorandum from R.L. Baum, Office of General Counsel, EPA, to Robert Sansom, EPA, March 26, 1973.

- 59 South Terminal Corp. v. EPA, 504 F.2d 646 (1st Cir. 1974); District of Columbia v. Train, 521 F.2d 971 (D.C. Cir. 1975).
- 60 Memorandum from R.L. Baum, OGC, to Regional Counsels, March 16, 1973.
- 61 This issue is still subject of dispute. Recently several courts have struggled with the issue and EPA may get its answer from the Supreme Court. See Brown v. EPA, 8 ERC 1953 (9th Cir. 1975), Maryland v. EPA, 8 ERC 1105 (9th Cir. 1975), Pennsylvania v. EPA, 500 F.2d 246 (3rd Cir. 1974), and D.C. v. Train, 521 F.2d 971 (D.C. Cir. 1975).

AUTOMOBILE EMISSION STANDARDS SUSPENSION

Raphael G. Kasper¹

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Automotive propulsion systems emit various air pollutants, among them carbon monoxide (CO), hydrocarbons (HC), and nitrogen oxides (NO_x). HC and NO_x, in the presence of sunlight, lead to the creation of photochemical oxidants such as ozone.

All of the pollutants are emitted to some extent from other sources as well as from automobiles. CO and HC are largely mobile source problems, but NO_x is emitted in significant amounts by both stationary and mobile sources. In fact, in only two of the ten largest metropolitan areas in the U.S. do NO_x emissions from mobile sources exceed those from stationary sources.¹

I. THE CLEAN AIR AMENDMENTS OF 1970

Although Federal regulation of automobile emissions began as early as the 1960s, this case study limits itself to examination of an EPA decision made under the 1970 amendments to the Clean Air Act. Those amendments proposed an elaborate program for the control of air pollution from all sources. (Currently, Congress is debating further revisions of the Clean Air Act.) Title II deals with emission standards from moving sources. EPA is required to prescribe standards applicable to the emission of any pollutant that causes or contributes to air pollution and endangers the public health and welfare. These standards are to take effect after the time necessary for development of the needed technology, giving appropriate consideration to the cost of compliance. (section 202(a))

The Clean Air Amendments are more specific about the required standards for the three principal automotive emissions:

The regulations...applicable to emissions of carbon monoxide and hydrocarbons from light duty vehicles and engines manufactured during or after model year 1975 shall contain standards which require a reduction of at least 90 percentum from emissions...allowable...in model year 1970. (section 202(b)(1)(A))

The Amendments continue:

The regulations...applicable to emissions of oxides of nitrogen from light duty vehicles and engines

manufactured during or after model year 1976 shall contain standards which require a reduction of at least 90 percentum from the average of emissions...actually measured...during model year 1971. Such average of emissions shall be determined by the administrator on the basis of measurements made by him. (section 202(b) (1) (B))

Emissions standards and measurement techniques were to be prescribed within 180 days. Automobile manufacturers were permitted to request a one-year suspension in any emission standard; if the suspension were granted, interim standards would be established which "shall reflect the greatest degree of emission control which is achievable by application of technology which the Administrator determines is available, giving appropriate consideration to the cost...." (section 202(b) (5) (C)) The criteria for a suspension are that:

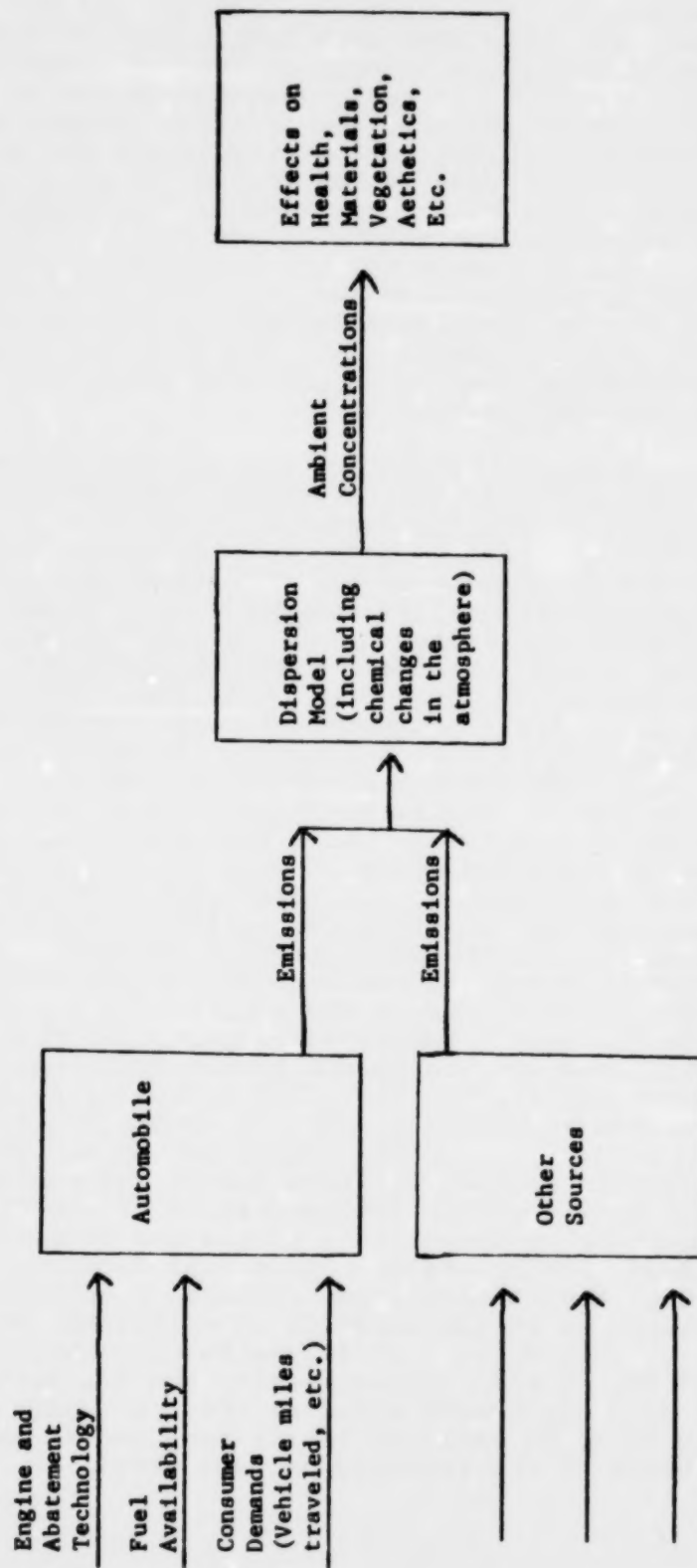
(i) such suspension is essential to the public interest or the public health and welfare of the United States, (ii) all good faith efforts have been made to meet the standards..., (iii) the applicant has established that effective control technology, processes, operating methods, or other alternatives are not available..., and (iv) the study and investigation of the National Academy of Sciences...and other information...has not indicated that technology, processes, or other alternatives are available to meet such standards. (section 202(b) (5) (D))

The law requires a study of "the technological feasibility of meeting the emissions standards" to be performed by the National Academy of Sciences. The law orders the Administrator of EPA to prescribe regulations under which the useful life of vehicles shall be determined but notes that: "...such regulations shall provide that useful life shall...in the case of light duty vehicles...be a period of use of five years or of fifty thousand miles...." (section 202(C) (4) (D) (1)) A fine of not more than \$10,000 is to be imposed for each offense under the law (i.e., for each vehicle or engine which does not meet the standards).

The simplified model of air pollution effects (see Figure 1) makes it clear that the motor vehicle standard sections of the Clean Air Amendments dictate a highly fragmented approach to decision making. EPA is given relatively little authority under these sections; the Agency can determine measurement techniques, it can determine what constitutes a 90 percent reduction in emissions, and it can grant single-year suspensions in certain of the standards. These decisions may have significant effects upon

FIGURE 1

SIMPLIFIED MODEL : AIR POLLUTION EFFECTS



investments by the automobile industry and the American consumer, but they deal with only a part of the overall problem of pollution control or even of automotive emission control. Ambient air quality standards are to be set under another part of the law; the relation between automotive emissions and ambient air quality is not an issue in EPA decision making, even in the regulation of automotive emissions. (The 90 percent reduction requirement assumes that a certain relationship exists between emissions and air quality, (as discussed below), but that relationship is not at issue in EPA decision making.) The cost of emission control can be considered in setting interim standards and, perhaps, under criteria (iii) and (iv), in allowing a one-year suspension; but it is not involved in the determination of the mandated standards.

The 90 percent reduction was derived from estimates by the National Air Pollution Control Administration, a predecessor of the Environmental Protection Agency, which calculated the minimum reduction in emissions necessary to insure the attainment of health-related air quality levels. (The ambient air quality standards had not yet been established; goals used in the calculation were: CO: 9 ppm, 8 hr avg (current standard = 9 ppm); Oxidants: .06 ppm, 1 hr avg (std = .08 ppm); NO₂: 0.10 ppm, 1 hr avg (std = .05 ppm yearly avg)).² A report by Barth formed the basis for the 90 percent reduction figures. In fact, there is every indication that the Barth report was the only piece of evidence used to determine the reduction in automobile emissions necessary to attain the ambient air quality goals. (There is something of an anomaly in this process of setting emission requirements; the 90 percent reduction was rationalized as necessary for achieving healthful ambient air quality, but the definition of healthful levels had not yet been provided and was left to the EPA Administrator in the setting of standards for ambient air quality.) Barth's calculation used a "modified proportional rollback model" which, in essence, assumed a linear relationship between emissions and air quality. The calculation also assumed that stationary sources would be controlled to the same extent as mobile sources. (This assumption is not reflected in pollution control programs and is not necessarily a logical result of the implementation of the Clean Air Amendments.) Rollback is a simple and understandable technique, but it neglects important factors, such as the height of the emissions and chemical reactions in the air. Uncertainties in the relation of emissions to ambient air quality still exist. To determine necessary reductions in HC and NO_x to meet oxidant goals, the NO_x emissions were set based upon NO₂ health effects; then, assuming this level of NO_x control, HC emission levels were set to assure attainment of the required oxidant level.

There has been considerable discussion of the intent of Congress in passing Title II of the Clean Air Amendments. Prior to enactment of the Amendments, automobile emission standards were to be based on a test of technical and economic feasibility. The provision in the 1970 Amendments which established statutory standards for emissions from passenger cars and which required achievement of those standards by 1975 and 1976 reflects what appears to have been frustration with the pace of automotive emission control. Concerned about the slow rate of progress in the late 1960s, Senator Muskie said on September 21, 1970, "...it is now clear that continued reliance on gradual reductions in automotive emissions would make achievement of the ambient air quality standards impossible within the national deadlines established in Title I of this act."³ He noted and emphasized that "the deadline is based not...on economic and technological feasibility, but on considerations of public health."⁴

The legislative history of the Clean Air Amendments makes clear that it was the intent of the law to force the automobile manufacturers to develop pollution control technology more rapidly. At the time the provisions were passed, technology for meeting the standards did not exist and there was considerable debate as to whether it could be developed in time to meet the standards. As might have been expected, the automobile manufacturers opposed strict emission standards on the grounds that the technology had not been demonstrated. John Goldsmith of the California Department of Public Health disagreed in hearings before a Senate Committee; he noted that the California experience had been to set air quality criteria and motor vehicle emission standards "before it was known that the motor vehicle industry would be able to meet the standards which we established," and the result was an improvement in automobile emission characteristics.⁵ William Ruckelshaus, former Administrator of EPA, speaking at a meeting of the NRC's Committee on Environmental Decision Making on March 14, 1975, indicated that, in his opinion, the automobile emission standards section of the Clean Air Amendments has in fact forced the industry to make significant progress in emission control. (There are many who agree with this contention; others, however, feel that the strict standards and condensed timetable for meeting them have forced the industry toward excessive reliance upon catalyst technology while limiting opportunities to pursue other, perhaps more promising, avenues to emission control. This case study does not enter the debate.)

II. THE FIRST SUSPENSION DECISION

Following passage of the Clean Air Amendments, EPA had a number of decisions to make despite the extreme specificity

of the law. It was the task of the Agency to determine the precise standards for allowable emissions and to devise the test procedures to be used to assure compliance. The law left other questions unanswered: Must all vehicles meet the standards, or does the law apply to average emissions? What maintenance is allowable within the useful life of the vehicle? (Although the decisions of the Agency on each of these issues were significant, this case study focuses only on the subsequent suspension decision.)

One other policy decision has had a major effect upon automobile emission control programs at EPA. At his meeting with the Committee on Environmental Decision Making, former EPA Administrator Ruckelshaus stated that it was Agency policy in the first few years after EPA was formed to attempt to enforce the laws as written, and that EPA would not return to Congress to request changes in statutory language or provisions. Given this policy, EPA did not have the options of altering the requirement for a 90 percent reduction in emissions or of extending the deadlines for more than one year.

In May of 1971, the Administrator of EPA conducted public hearings on the activities of automobile manufacturers in attempting to comply with the provisions of the Clean Air Amendments. The hearings were held to elaborate and explain the response to a February 1971 questionnaire which EPA had sent to the manufacturers seeking to determine what development activities were underway. One reason for the hearing was to give the Administrator an early look at whether the manufacturers were making "good faith" efforts since, in the event of a decision on suspending the standards, the Administrator would have to determine whether good faith efforts were underway. A second questionnaire was sent in October 1971 and all the information obtained was reviewed by EPA's Bureau of Mobile Source Pollution Control in the Office of Air Programs. In January 1972 that office issued an in-house evaluation of the state-of-the-art of emissions control.

Also in January 1972, the National Academy of Sciences published its first interim report as required in section 202 of the Clean Air Amendments. Working under contract to EPA, the Academy's Committee on Motor Vehicle Emissions (CMVE) had examined the technological feasibility of designing, mass producing, and maintaining emission control systems capable of meeting the standards. The CMVE had established seven panels of consultants to examine major topics (emission standards; testing, inspection, and maintenance; emission control systems; alternate power sources; manufacturability and producibility; driveability; and atmospheric chemistry). The panels had concentrated initially on issues related to standards for 1975 model

cars. The panels had obtained information from domestic and foreign automobile manufacturers and had visited domestic automobile manufacturers, EPA laboratories, the U.S. Army Tank-Automotive Command, catalyst suppliers, manufacturers of testing equipment, and the California Air Resources Board. The January 1972 report commented that:

The vast majority of the engines used in the 1975 model year vehicles will inevitably be conventional reciprocating spark-ignition internal combustion engines.... Though engine modifications to reduce emissions are likely to be incorporated, the basic geometry and operation of the engine will be similar to what it is today.*

The report noted:

...it is clear that no major manufacturer has yet demonstrated the technology needed to meet the requirements...of 1975 model year vehicles. However, both the automobile and catalyst manufacturers have intensive development efforts under way. Thus there remains some possibility that a control system can be developed in time to permit the mass production of vehicles that will meet the 1975 standards.7

Stressing that the major automobile manufacturers were at different stages in their development efforts, the CMVE report concluded that:

...the technology necessary to meet the requirements of the Clean Air Amendments for 1975 model year light-duty vehicles is not available at this time.... While there is no certainty today that any 1975 model year vehicles will meet the requirements of the Act, the status of development and rate of progress make it possible that the larger manufacturers will be able to produce vehicles that will qualify....*

The report discussed in detail some of the technical difficulties that manufacturers faced in meeting the 1975 standards (e.g., catalyst durability and maintenance) and included a discussion of the consequences of a one-year suspension of the 1975 standards. Noting that even experimental vehicles had not yet been able to meet the 1975 standards for 50,000 miles, the report suggested that "one important advantage of a one-year suspension...is that it would allow an additional year's work on development...."9 The suspension would also allow time for additional testing of durability and reliability and would "help to ensure the nationwide availability of (low lead) fuel...."10 The report also noted that the effect of a one-year suspension

on total vehicle emissions (and presumably on air quality) "appears to be small."¹¹

On March 13, 1972, A.B. Volvo, Ltd., of Sweden filed an application for suspension of the 1975 emission standards. Shortly thereafter International Harvester, Ford, General Motors, and Chrysler applied for suspensions. A public hearing was held (April 10 to 27, 1972) during which testimony was received from 49 individuals and organizations.

Participants in the hearing recall the process as a learning experience for every one involved. The hearing panel, composed of the Administrator accompanied by some of his technical and legal staff, was operating under tight statutory deadlines. Cross examination was not permitted at the hearing "because of the need to make a decision within the 60 day statutory deadline."¹² Despite the lack of cross examination, however, discussion of questions from technical members of the panel often developed into dialogues between panel members and company witnesses with questions and answers coming from both sides. At the hearings, the Administrator "emphasized that the final decision would be his and his alone."¹³

The manufacturers presented results of vehicle tests that had been performed by 13 companies. The tests showed that only one car had conformed to the standard and that none had actually been driven 50,000 miles (the useful life of a vehicle).

Not all the testimony presented at the hearing supported the suspension request. Companies such as catalyst manufacturers and those with an interest in the use of tetraethyl lead argued other positions. On May 12, 1972, EPA Administrator Ruckelshaus denied the applications for suspension on the grounds that he could not make the determinations required under section 202(b) (5) (D) (i), (iii), (iv) of the Clean Air Amendments. The Administrator held that he was required by law to make each of the four determinations required in section 202(b) (5) (D) (see p. 3 of this paper). Thus, he said, under the law

I cannot grant a manufacturer's application on the basis of a judgement on my part that it is in the public interest to suspend the standards if I cannot also make the separate statutory determinations concerning good faith and technical feasibility.

He continued:

...the Act does not permit suspension of the standards if information presented by the

applicants or obtained from other sources is inconclusive as to any of the required determinations.¹⁴

But Ruckelshaus noted that uncertainties will always exist; he held that he did not interpret the law as requiring

...absolute conviction or certainty before a suspension can be granted, for it must be recognized that an attempt to assess the effectiveness and availability of present technology to achieve future compliance by mass produced vehicles is extremely difficult and may never be wholly free from doubt.¹⁵

He thus insisted only that the determinations required in the law be made with "reasonable confidence." He noted:

For these reasons I reject the argument...that the standards may lawfully be suspended where the effectiveness of available control technology cannot itself be affirmatively established or has not been "proved".... Under the law it is the applicants who must establish the ineffectiveness or nonavailability of control technology....¹⁶

The placement of the burden of proof (or persuasion) is interesting and results from a literal reading of section 202(b) (5) (D) (iii) which begins: "The applicant has established that...." Clarence Ditlow has said that "the simple shift in the burden of proof was the decisive factor in this decision."¹⁷

In Ruckelshaus' judgment, promising new technology should be given consideration in determining the technical feasibility of achieving compliance. He added a comment on the guidance that the statutory language provided in this regard:

Neither the statute nor its legislative history offers specific guidance as to precisely what kinds of impediments to producing the full range of light duty vehicles presently sold in the United States, or what kinds of potential liabilities associated with the production of new automobiles in 1975, can be regarded as constituting inability to comply with the standards.¹⁸

Ruckelshaus noted that Congress clearly intended to "force" the technology of emission control in passing the Clean Air Amendments:

There is no basis, therefore, for construing the Act to authorize suspension of the standards simply

because manufacturers may be required to produce fewer varieties of light duty vehicles in 1975 or because the range of performance of cars with effective emission control may be restricted as compared to present cars.¹⁹

One issue of some importance in the decision was whether a need for changing a component of the emission control system during the useful life of the vehicle renders the system not "effective" under the law. Ruckelshaus held that reasonable maintenance, including possible replacement of catalytic converters, was permitted for "effective" systems. Some have held that this reading of the law "seems strained, at best."²⁰

The Administrator saw numerous problems in the test results that had been submitted by the manufacturers (e.g., the fuel and oil used were not always specified, tests were not repeated, few cars were driven even as much as 20,000 miles) and noted that:

In the face of these difficulties, analysis and interpretation of the data required assumptions and analytical approaches which will necessarily be controversial to some degree.²¹

The Administrator made adjustments in the test data (some of which actually resulted in a prediction of increased emissions). These adjustments took into account lead content of gasoline; the fact that attempts to reduce NO_x emissions (not required for 1975 in the statute) had resulted in increased HC and CO emissions; the assertion, by the Administrator, that "some manufacturers' assumption as to probable deterioration (of catalysts) after 4,000 miles have been unjustifiably conservative;"²² prototype-to-production slippage; and the allowance of a single catalyst change. In Ruckelshaus' judgment:

...no applicant has established that effective control technology, processes, operating methods, or other alternatives are not available or have not been available for a sufficient period of time to achieve compliance.... While the technical feasibility of compliance is a close issue, it is my further judgement that information in the record of this proceeding indicates that presently available control technology is effective within the meaning of the Act to achieve compliance with the standards by the statutory deadline. At the very least, I am compelled to conclude that information indicating that the standards are achievable is as persuasive as is information which indicates that they are not achievable. In reaching these conclusions I have considered the

reports submitted by the National Academy of Sciences under...the Act.²³

The decision included, as an appendix, a description of procedures used in arriving at the decision. They included:

- questionnaire to manufacturers on technology
- NAS study
- public hearings on how manufacturers were complying
- second questionnaire
- in-house "technology assessment"
- application for suspension
- subpoenas to automobile manufacturers
- public hearing

The information on which the decision was based was listed:

- (1) information from first round of hearings;
- (2) written responses to questionnaires;
- (3) NAS studies;
- (4) the facts and judgments compiled in EPA's in-house 'Technology Assessment' report; and
- (5) information from suspension hearings.

At least one group of lawyers feels that the Administrator "read the provisions allowing him to grant a one-year postponement in a peculiarly restrictive manner" when he found that he had to make all four determinations in section 202 (b) (5) (D) of the Act.²⁴ (Note: This author disagrees; in his opinion the statement that A shall do X only if he determines that i, ii, iii, and iv means quite clearly that four determinations must be made.) Noting that the Administrator's decision had been overruled, the lawyers found the decision interesting, nonetheless, for its indication of the Administrator's reading of Congressional intent:

Not only did he find it necessary to comply most specifically with the requirement of the Act that he make separate findings on each of the four conditions for a suspension, but he also placed a heavy burden of persuasion on the manufacturers....

The opinion also throws light on the Administrator's willingness to read the Act as a whole and to draw on provisions not directly involved in the granting of the suspension to cast light on the degree of technical compliance to be exacted. The reading of the maintenance provision of the law...to allow catalyst replacement during the useful life of the vehicle furnishes the most significant example of this interpretational technique.²⁵

III. THE INTERNATIONAL HARVESTER CASE

Four automobile manufacturers appealed the Administrator's decision. After oral arguments in December 1972, the Court of Appeals for the District of Columbia Circuit remanded the record to the Administrator for the purpose of obtaining a supplement to his decision that would explain the relationship between the Administrator's decision and the National Academy of Sciences report which had concluded, in part, that technology to meet the 1975 standards was not currently available. In a supplement to his decision, issued December 20, 1972, the Administrator noted that, in general, his findings were consistent with those of NAS. This statement was based upon the recognition in the NAS report that the rate of progress of the industry made it possible for certifiable vehicles to be built by the 1975 model year. On February 10, 1973, the Court remanded the applications to EPA for reconsideration (International Harvester v. Ruckelshaus) holding that the Administrator's consideration of the availability of control technology was inadequate.

In the decision Judge Leventhal noted that "it is not without diffidence that a court undertakes to probe even partly into technical matters of the complexity of those covered in this opinion."²⁶ Notwithstanding its diffidence, the Court proceeded to examine the technical issues which "permeate the 'available technology' determination" upon which the Administrator based his decision. Calling attention to

the number of unexplained assumptions used by the Administrator, the variance in methodology from that of the National Academy of Sciences, and the absence of an indication of the statistical reliability of the prediction....²⁷

The court expressed "grave doubts as to whether technology is available to meet the 1975 standards."²⁸ The industry had presented evidence from tests that the technology was not available:

The Administrator's reliance on technological methodology to offset the actual tests raised serious doubts and failed to meet the burden of proof which in our view was properly assigned to him, in light of accepted legal doctrine and the intent of Congress discerned, in part, by taking into account that the risk of an "erroneous" denial of suspension outweighed the risk of an "erroneous" grant of suspension.²⁹

The International Harvester decision has been the subject of considerable attention in the legal literature and this case study cannot consider all the ramifications of the decision. However, for our purposes here, two aspects of the decision warrant further discussion; the Court's evaluation of the manner in which the technical analysis was carried out, and the apparent broadening of the social and economic grounds upon which a decision should be made.

The Court considered the Administrator's analysis of the availability of technology in some detail. The decision held that the Administrator's contention that the manufacturers did not submit sufficient evidence to allow him to determine that technology was not available was incorrect. The Court stated that "the companies came forward with all the data that there was to be had and the Administrator did not specifically ask for more."³⁰ The Court held that the law did not require proof beyond a reasonable doubt and that this was, in effect, what the Administrator seems to have required in his decision. Noting that the underlying issue is the reasonableness and reliability of the Administrator's methodology, the court held that the Administrator must bear the burden of demonstrating reasonableness and reliability. The decision stated that "the multiple assumptions used by the Administrator in making his prediction (of availability) are subject to serious doubts."³¹ This was followed by a detailed discussion.

The Court seems to have rejected the Administrator's Supplemental Decision which held that the EPA decision was consistent with the National Academy of Sciences conclusions. The Court noted that the National Academy of Sciences had concluded that technology was not available to meet the standards in 1975. While noting that the statute makes the NAS conclusion a necessary, but not sufficient, condition of suspension, the Court

... (did) not think that it was contemplated that EPA could alter the conclusion of NAS by revising NAS assumptions, or injecting new ones, unless it states its reasons for reliability....³²

Judge Bazelon concurred in the result but was disturbed by the Court's embarking on a substantive review of the technical evidence:

I cannot believe that Congress intended this Court to delve into the substance of the mechanical, statistical, and technological disputes in this case.

He noted:

My grounds for remanding the case rest upon the Administrator's failure to employ a reasonable decision making process for so critical and complex a matter.

The Court must insist on a process which "adequately...protect(s) the interests of all 'consumers' of the natural environment." Bazelon continued:

...in cases of great technological complexity, the best way for courts to guard against unreasonable or erroneous administrative decisions is not for the judges themselves to scrutinize the technical merits of each decision. Rather, it is to establish a decision-making process which assures a reasoned decision that can be held up to the scrutiny of the scientific community and the public.³³

In its decision, the Court noted the importance of technical issues but insisted that "at the same time...larger questions are at stake."³⁴ If the Administrator were upheld and later found to be incorrect "grave economic consequences could ensue."³⁵ If the Administrator were overruled and the suspension granted but later evidence showed the Administrator to have been correct, "the environmental costs...are likely to be modest."³⁶ The costs of a wrong decision must be taken into account, the Court stated; impacts of a denial of suspension on jobs, the economy, and technological progress must be weighed against environmental improvements which could result from such a denial. This part of the decision has been interpreted by some, apparently including Ruckelshaus, as broadening the basis for a decision on the suspension by allowing the Administrator to weigh competing social considerations. There are those who feel the International Harvester decision reflected a change in public attitudes toward environmental protection decisions--a movement away from the zeal of the early 1970s. Others, noting that the decision came not long after the overwhelming rejection of the veto of the Federal Water Pollution Control Act, suggest that the decision presaged rather than reflected a change in attitude.

As might have been expected, different interests viewed the expansion of the grounds for a suspension decision differently. While some applauded the decision, Ditlow voiced his dismay:

In this decision, the Court of Appeals put back into the Clean Air Act what Congress had so carefully legislated out with the 1970 Amendments -- considerations of economic costs.³⁷

Thus the court remanded and required that limited rights of cross examination be permitted on new lines of testimony.

IV. THE DECISION ON REMAND

Several days after the decision of the Court in the International Harvester case, the National Academy of Sciences' Committee on Motor Vehicle Emissions made its final report to EPA. The CMVE concluded that for 1975 model year vehicles

1. Four types of systems will meet the prescribed emissions standards during certification testing (if provisions are made for averaging emissions test results)....
2. Vehicles incorporating these systems can be mass produced in great enough volume....
3. It is important...that a suitable maintenance and inspection system be established....³⁸

The CMVE was careful to point out that although catalyst equipped vehicles might be produced which could be certified for 1975, "compliance with the certification procedure, of itself, may not constitute indication of satisfactory performance of catalyst equipped vehicles in actual customer use."³⁹ The CMVE expressed concern over the possibility of frequent catalyst failure under conditions of actual use.

The Committee addressed the question of the technology forcing aspects of implementation of the Clean Air Amendments. Noting that more stringent NO_x controls would have to be applied to 1976 model year vehicles, the report noted:

Some members of CMVE are concerned that strict enforcement of the provisions of the Act might, by forcing adaption of the control system first to be developed and certified, defeat the goal of the earliest possible attainment of compliance by the most generally desirable means. These members of CMVE believe that, once having embarked upon large-

scale production of the catalyst-dependent control systems, several years would elapse before major manufacturers would alter course in favor of producing more satisfactory vehicles.*0

A minority of the members of CMVE urged rigorous enforcement of the Act since there was no assurance that delay would be put to any productive use by the manufacturers. But the majority of the Committee, noting uncertainties about catalyst reliability and potentially detrimental effects of industry focus upon a single control technology (catalysts), suggested that:

...on balance, it may be prudent for EPA to consider a delay in the imposition of 1975 and 1976 standards, but no longer than that provided for in the Act. It is thought that this would provide the manufacturers an opportunity to consider and implement alternative and, quite possibly, more generally satisfactory technologies with which to attain the goals of the Act. In this view...such an action would not result in an unacceptable deceleration in reduction of automotive emissions.*1

Thus, although CMVE had found that catalyst systems were technologically feasible, it still recommended a delay in implementation of the standard. One reason for this was the development of a stratified-charge engine by Honda in Japan. This engine showed great promise, and CMVE apparently felt that a delay in enforcement of the standards would allow further development.

EPA held two weeks of public hearings beginning March 12, 1973 to consider the remanded applications. On April 11, 1973, Ruckelshaus granted the one-year suspension and set interim standards for California and the rest of the country for 1975. The California standards were stringent enough to require catalysts on domestic cars sold in that state.

Attributing the change in the criteria for making a decision to the principles articulated by the Court of Appeals, Ruckelshaus saw his decision as one of determining "the most reasonable method by which necessary technology will be installed on automobiles."*2 The decision to require the use of catalysts on a significant number of 1975 automobiles (those sold in California) while granting a suspension of the standards for the rest "best serves the public interest and the mandates of the statute."*3

Ruckelshaus applied the "public interest" criterion to his analysis of the availability of the technology. He commented on the progress which had been made in the eleven

months since he had made his original decision. A great deal of attention was paid to catalyst durability, but Ruckelshaus concluded that the development of technology "holds promise" for meeting the standards. (This qualitative description of the state of technology is similar to the description in the first NAS report and in the 1972 suspension decision.) Ruckelshaus found that presently available technology probably could meet the certification requirements. But, reflecting the concern of the Court of Appeals, he added:

However, I also believe that there is significant risk that this determination would prove to be erroneous and that manufacturers would not be able to successfully certify vehicles at the statutory levels in sufficient numbers to meet basic demand....**

As to mass production, Ruckelshaus found that it would be feasible to mass produce catalyst-equipped cars but that requiring catalysts on all cars would create a "risk of economic dislocation" due to a possible shortage in the supply of acceptable catalysts. The risks of dislocation "must be considered to outweigh the slight gain in air quality that might result from requiring catalysts on all cars."**

Ruckelshaus used the decision document to describe the methodology applied in evaluating the data. Having been criticized once before for not being sufficiently explicit about the analysis, Ruckelshaus commented that his staff had attempted to demonstrate the reliability of the methodology,

...striving to avoid the features criticized by the Court in last year's decision and in no case relying on assumptions which were not supported by data or reasoned analysis.**

The data received from manufacturers, while clearly "germane and relevant," was only raw data; the EPA methodology had to select from the data and adjust the data where appropriate. The EPA methodology had been discussed with the automobile manufacturers. Since much of the manufacturer's data was based on "less-than-best" systems, it was clear that adjustments were necessary to project system performance and availability for the future.

Recalling the emphasis placed by the Court on the NAS report, Ruckelshaus devoted a portion of his decision to a discussion of the consistency of his decision with the NAS conclusions. The NAS study had been performed before the Court's decision so the CMVE did not know that the Court would require that "public interest" should be a dominant feature in any suspension decision. The NAS Committee had concluded that technology was available to meet the

standard; but when it applied a "public interest" yardstick, it recommended a one-year suspension.

It is clear that the requirement of a "public interest" balancing of risks and benefits was the determining factor in the 1973 decision. While a year of progress had been made since the initial decision, the technical basis for the decision had not changed in a qualitative sense. That is, it still seemed that the technology could be available with some questions about how durable it would be in use. (If anything, the purely technical analysis of availability of technology was somewhat more optimistic in 1973 than in 1972 although, throughout the period, uncertainties about the reliability of the prediction remained.) In 1972, Ruckelshaus' literal reading of the statute led to a denial of the suspension request. In 1973, faced with the Court's decision requiring a public interest test that would weigh the possible consequences of an incorrect decision, Ruckelshaus was almost forced to grant the suspension.

V. DISCUSSION

A number of additional issues deserve mention at this point since they may illuminate certain generic problems of environmental decision making.

The basic information used by the Administrator in his 1973 decision came from emission tests performed by the automobile manufacturers. Development of "perfect" information would have required tests of all proposed systems for a full 50,000 miles. Neither time nor resources allowed such tests. Thus the Administrator was faced with the problem of predicting future emissions from hypothetical (or at least not fully tested) systems. It seems clear that the intent of the legislation was to force the development of new or improved technology and not merely to require the use of already existing technology. Thus the role of the Administrator as a predictor was at least implicitly assumed in the legislation.

As noted earlier, the first decision of the administrator turned upon his definition of "available" systems. Since much of this determination depended, in turn, upon his projection (prediction, guess?) as to future developments in the industry, it is not clear whether any more information (beyond the manufacturers' test reports and the NAS report) would have had a significant effect on the decision.

The case raises an interesting issue that confronts EPA in other areas as well. The basic information came from a party with a direct interest in the outcome of the decision, the automobile manufacturers. This is understandable; the

industry possessed the technical ability and resources to perform the tests. But the situation created a dilemma for the decision maker who had to determine whether the industry had made "good faith" efforts to reduce emissions. Such a determination had to be, by its very nature, subjective. An Administrator who was skeptical about the intent of the industry (as the Congress clearly was when the Clean Air Amendments were passed) might require a different standard of proof for "good faith" efforts than one who was not skeptical. No objective criteria existed (or could have existed) for determining whether the manufacturers were making their best effort. The Congress provided one means of aiding the Administrator in his evaluation of industry performance; it required the preparation of a report by the National Academy of Sciences which would independently examine the technical feasibility of meeting the standards. ("Independently" may not be a correct characterization; NAS also had to rely, in large measure, on information from the industry. That such reliance can create problems is evident; some members of CMVE, for example, are known to have been disturbed about the reluctance of the industry to provide complete and timely information about the development of the stratified-charge engine.) The NAS study provided the Administrator with an expert review of the information made available by the industry. Since the NAS Committee was not required to make a decision, its report was written in such a manner that it could be interpreted differently by different readers. (Witness the disagreement between the Court of Appeals and the Administrator over the interpretation of the January 1972 report.) However, it can be argued that an ambivalent report (the technology could be available, but it might not stand up in actual use) provided the best possible statement of the current state of knowledge. To have gone further, to have been unequivocal in its conclusions, the NAS Committee would have had to make judgments that it had no competence to make. The social, economic, and environmental trade-offs were in the province of the Administrator; the NAS reports made it clear that those trade-offs would have to be assessed on the basis of uncertain information.

It seems that Ruckelshaus' initial reaction to the automobile emissions standards provisions of the Clean Air Amendments was similar to the Congressional intent in passing them. That is, he saw them as a means of forcing the industry to develop new or better technology quickly. He applied the conditions for a suspension literally and strictly at first.

The importance of judicial review in Agency decision making is evident in this case. The decision of the Court of Appeals shifted the grounds for the Administrator's decision from technical consideration of systems availability to a more general examination of the public

interest. It marked an instance of a Court delving into substantive matters, and it forced the Administrator to provide an explicit and defensible record in his decision on remand. (I leave to lawyers a determination of whether the decision process was made any clearer on remand than it was initially; in my opinion, EPA was quite explicit in both cases about how its decisions were made.)

An interesting follow-up issue could be the effect of the International Harvester decision on subsequent suspension decisions. A quick reading of the latter indicates that the International Harvester case appears to have created a climate that favors granting suspension requests rather than denying them. Since current versions of revisions of the Clean Air Act provide for some degree of suspension authority for EPA, the precedents of the International Harvester case may continue to be an important factor in EPA decision making.

NOTES

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- 2 D. Barth, "Federal Motor Vehicle Emission Goals for CO, HC, and NO, Based on Described Air Quality Levels."
- 3 Edward Muskie, Senate Debate on S. 4358, September 21, 1970, reported in "A Legislative History of the Clean Air Amendments of 1970," Vol. 1, p. 228 (Senate Committee on Public Works, January 1974).
- 4 Ibid., p. 239.
- 5 Hearings before Subcommittee on Air and Water Pollution, Senate Committee on Public Works, 90th Congress, 2d Session, Pt.2, p. 549.
- 6 Committee on Motor Vehicle Emissions (NAS) January, 1972, p. 10.
- 7 Ibid., p. 30.
- 8 Ibid., p. 219.
- 9 Ibid., p. 45.
- 10 Ibid., p. 45.
- 11 Ibid., p. 48.
- 12 Decision of the Administrator. In re: Application for Suspension of 1972 Motor Vehicle Exhaust Emission Standards, May 12, 1972, Appendix A, p. 3.
- 13 Ibid., Appendix A, p. 4.
- 14 Ibid., p. 7.
- 15 Ibid., p. 7.
- 16 Ibid., p. 7.

- 17 Clarence Ditlow, "Federal Regulation of Motor Vehicle Emissions Under the Clean Air Amendments of 1970," Ecology Law Quarterly, Vol. 4, 1975, pp. 495,512.
- 18 Decision of the Administrator. In re: Application for Suspension of 1975 Motor Vehicle Exhaust Emission Standards, May 12, 1972, p. 9.
- 19 Ibid., p. 9.
- 20 Grad, Rosenthal, Rockett, etc., The Automobile and the Regulation of Its Impact on the Environment, p. 342.
- 21 Decision of the Administrator. In re: Application for Suspension of 1975 Motor Vehicle Exhaust Emission Standards, May 12, 1972, p. 17.
- 22 Ibid., p. 18.
- 23 Ibid., p. 13.
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- 25 Ibid., p. 345.
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- 27 Ibid., p. 20148.
- 28 Ibid., p. 20148.
- 29 Ibid., p. 20148.
- 30 Ibid., p. 20145.
- 31 Ibid., p. 20145.
- 32 Ibid., p. 20148.
- 33 Ibid., p. 20149.
- 34 Ibid., p. 20139.
- 35 Ibid., p. 20139.
- 36 Ibid., p. 20141.
- 37 Ditlow, supra note 17, p. 513.
- 38 NAS Committee on Motor Vehicle Emissions, 1973, p. 2,3.
- 39 Ibid., p. 115.
- 40 Ibid., p. 125.

- 41 Ibid., p. 126.
- 42 Decision of the Administrator on Remand from the United States Court of Appeals for the District of Columbia.
In re: Applications for Suspension of 1975 Motor Vehicle Exhaust Emission Standards, April 11, 1973 p. 5.
- 43 Ibid., p. 6.
- 44 Ibid., p. 15.
- 45 Ibid., p. 18.
- 46 Ibid., p. 21.

MOUSE LIVERS, CUTWORMS, AND PUBLIC POLICY: EPA
DECISION MAKING FOR THE PESTICIDES ALDRIN AND DIELDRIN

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I. OVERVIEW

A. The Nature of the Decision

EPA's controversial 1972 ban of most uses of DDT was based primarily on the pesticide's adverse environmental effects. When the Agency turned to the chemically similar insecticides aldrin and dieldrin (A/D), new concerns arose. These major pesticides, present in the body tissues of most Americans, were found to cause cancer in laboratory mice at low dietary concentrations. EPA's task was to determine whether continued use of A/D was to be permitted, given the possibility that they are human carcinogens. The Federal Environmental Pesticide Control Act (FEPCA) gives EPA authority to control pesticide pollution through (1) cancellation of a product's federal registration, without which products cannot be sold, and, when "imminent hazard" is seen, (2) immediate suspension of the sale of a product during administrative proceedings on cancellation. Because insecticides are registered for specific uses (e.g., control of cutworms on field corn), the A/D policy assessment amounted to use-by-use consideration of the pesticides' risks and benefits.

B. The Action in Brief

EPA inherited the A/D controversy; along with DDT, A/D had been subjected to a number of special scientific reviews and to legal challenges by the Environmental Defense Fund (EDF) in the late 1960's. Until December 2, 1970, FIFRA (FEPCA's predecessor) had been administered by the U.S. Department of Agriculture (USDA), which, while declining to eliminate all A/D registrations, initiated an inquiry into the need for A/D and issued uncontested cancellations for some uses. On December 3, EDF submitted a petition to EPA asking the day-old agency to cancel and suspend all A/D registrations. EDF asserted that the chemicals cause severe environmental damage and pose a human cancer risk.

Administrator William Ruckelshaus issued a notice of intent to cancel A/D about four months later, emphasizing environmental hazards and only briefly mentioning the question of carcinogenesis. He declined, however, to suspend A/D registrations. Firms holding registrations for A/D exercised their statutory right to request scientific review by an advisory committee chosen from experts nominated by the National Academy of Sciences (NAS). The

committee's report, issued in March 1972, concluded that several major A/D uses (including the control of soil insects attacking corn) posed no threat to human health and recommended that they be continued.

In June 1972, Ruckelshaus affirmed his cancellation action for all but three uses that were seen as representing negligible hazard. Shell Chemical Company, the sole U.S. manufacturer of A/D, and other supporters requested the initiation of public hearings as specified in FIFRA. EDF and the National Audubon Society intervened in support of cancellation.

As both sides prepared for a formal trial-type hearing before an EPA Administrative Law Judge (ALJ), the major parties vainly attempted to negotiate a settlement based on severely restricted product labelling, voluntary cessation of A/D production within two or three years, and a public statement of findings of fact concerning the human and environmental effects of the pesticides' use.

Cancellation hearings began in August 1973. A year later they were still under way, with no end clearly in sight. On August 2, 1974, when the cancellation hearing had amassed some 35,000 pages of transcript and exhibits, Administrator Russell Train announced the immediate suspension of A/D, explaining that new information persuaded him that another season of A/D use would present imminent hazard to man and the environment. An expedited 15-day hearing on suspension followed.

Judge Herbert Perlman issued his recommended decision favoring suspension on September 20. Administrator Train suspended A/D on October 1, 1974. In April 1975, the D.C. Appeals Court upheld the Administrator's decision to suspend. Two weeks later Shell indicated that it would no longer sell or produce A/D for any use in the U.S., and Judge Perlman recommended cancellation of all previously contested registrations. The cancellation decision became final on June 30, 1975.

C. Policy Issues

The aldrin/dieldrin case had an abundance of factual disputes. Such complexity is to be expected of a matter that was before the Agency for nearly 1700 days and for which the complete written record commands some 60 feet of shelf space. The primary emphasis in this case summary is placed on the two central issues, cancer and corn. The main policy questions:

1. What constitutes an adequate indication that a substance is carcinogenic in humans?

Quite apart from the question of the particular toxicological characteristics of A/D, there was extensive debate on what evidence on any substance would make appropriate grounds for a finding of human health hazard. Conclusive human effects data were unavailable, so the question became one of what other evidence could be properly associated with human susceptibility. The EPA trial staff ultimately proposed nine "established principles of carcinogenicity" that were distilled from the testimony of scientists at the A/D cancellation hearings. These general statements later appeared as elements of both the ALJ's proposed findings and Train's suspension decision. The principles included such statements as: "introduction of benign tumors is sufficient to characterize a chemical as carcinogenic," "the concept of a 'threshold level' for a carcinogen has no practical significance," and "carcinogenicity can be determined through laboratory testing of experimental animals such as mice and rats." The debate generated on this crucial question is treated in detail in the companion case study, "Explicit Criteria and Principles for Identifying Carcinogens," by Nathan J. Karch.

2. Does A/D represent carcinogenic risk to humans?

After reviewing original data from published studies, the trial staff claimed that there were indications of malignant tumor induction in five strains of mice and the rat (however, the ALJ and Administrator were less certain of the rat findings); the Agency dismissed Shell's arguments that epidemiological studies failed to show cancer incidence in exposed individuals. Shell conceded the mouse data on carcinogenesis, but argued that the observed effect was unique to the mouse liver. EPA witnesses' interpretations of rodent data were vigorously controverted, and Shell emphasized the absence of conclusive evidence of human risk.

3. Would elimination of A/D have adverse effects on the farm economy?

This debate was largely restricted to corn, and, further, to corn production in the eight-state Corn Belt where most aldrin corn use occurs. EPA held that substitute insecticides were available for pests controlled by aldrin. Shell argued that, particularly for the cutworm, satisfactory alternatives were unavailable, that farmers' costs would increase while their yield fell, and that consumers would pay millions in higher corn prices.

II. THE REGULATORY CONTEXT

A. The Pesticide Statute

Initial EPA action against A/D was taken under the 1947 FIFRA. A major statutory overhaul was signed on October 21, 1972,³ and later actions were considered to fall under the amended FIFRA, known as the Federal Environmental Pesticide Control Act (FEPCA).⁴

1. Registration

The old law prohibited interstate shipment of "economic poisons" unless the seller held a valid federal registration. Registration could be denied for "misbranded" products, including pesticides "which, when used as directed in accordance with commonly recognized practice, are injurious to man, vertebrate animals or vegetation."⁵ About 35,000 product registrations were in effect when EPA absorbed the USDA program in 1970.⁶ Registration involves federal approval of product labelling; labels must specify the pest to be controlled, the crop treated, and any use restrictions necessary to prevent hazard.

To support registration, applicants are required to submit at least minimal research data on the compound's characteristics. Data requirements have increased over the years and now can include, depending on expected use, studies on acute and subacute toxicity, oncogenicity (tumor induction), reproduction, teratogenicity (induction of birth defects), mutagenicity, pesticidal efficacy, and environmental fate. Data from registration files played a very small part in the A/D proceeding.

2. Cancellation

The A/D cancellation notice came in the wake of a January 1971 appeals court decision on DDT concluding that, even after registration, registrants carry a continuing burden of proof that their products meet statutory safety standards, and that the Administrator must initiate cancellation action whenever available data indicate a "substantial question of safety."⁷ The court found, however, that a final cancellation decision "does not turn on a scientific assessment of hazard alone. The statute leaves room to balance the benefits of a pesticide against its risks."⁸ Under the old statute, registrants who received notice of cancellation could have the matter referred to an advisory committee of experts nominated by NAS for a 60-day review. If the cancellation notice was thereafter affirmed by the Administrator, registrants were entitled to request a full public hearing before an

Administrative Law Judge. The Administrator ultimately reviews the judge's recommended decision and decides whether to cancel a registration. To date, EPA has completed cancellation procedures for three major pesticides (DDT, A/D, and mercurials), and is engaged in marathon cancellation hearings on heptachlor/chlordane (H/C).

3. Suspension

The Administrator can suspend a pesticide's registration if necessary to prevent "imminent hazard" caused by a pesticide's use during the time required for cancellation proceedings.⁹ FEPCA defines imminent hazard, in part, as "unreasonable adverse effects on the environment,"¹⁰ which is further defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide."¹¹ Following a suspension notice, registrants can request an expedited formal hearing. The Agency has suspended A/D and H/C.

4. Use Control

Short of outright cancellation and suspension, EPA can only rely on user compliance with directions on product labels to prevent harm from misuse or overuse of pesticides. The 1972 FEPCA added two new control provisions; the more hazardous "restricted" class of pesticides are to be applied only under the direction of government-certified applicators, and, according to the statute's Section 12(a) (2) (G), "use inconsistent with the labelling" is now an illegal act. The applicator provision had not yet been implemented during the A/D proceedings, and the imposing political and practical barriers to meaningful enforcement of the "misuse" clause made policy options based on label changes seem toothless to those who considered A/D a serious health risk.

B. Principals in the Case

Within EPA, the center of action for much of the A/D proceeding was the Office of General Counsel (OGC). Day-to-day management of EPA's case, including coordination of fact finding, was conducted by OGC attorney John Kolojeski, leader of the A/D litigation team. Personnel in the Agency's pesticide office played supporting roles to the lawyers.

Cancellation and suspension hearings for A/D were both conducted under trial-like conditions before Administrative Law Judge Herbert L. Perlman. Administrative Law Judges,

while paid by the Agency, enjoy nominal independence from EPA in that they rely on the Civil Service Commission for advancement and they have career tenure. The Administrator plays a role analogous to an appellate court in EPA adjudicatory hearings, and must be isolated from ex parte contacts with interested parties (including the EPA trial staff) on matters relating to a case he will receive for review. The Administrator's decision, in turn, may be appealed to a U.S. Court of Appeals by intervenors in the case; in the A/D matter, appeals were heard by the U.S. Court of Appeals for the District of Columbia Circuit.

Shell Chemical Company (a division of Shell Oil Company) and 22 other A/D registrants were active parties to the cancellation and suspension hearings, with Shell providing most of the suppliers' case. The Department of Agriculture and an association of Florida citrus producers were the most active representatives of A/D users. EDF and the National Audubon Society made joint presentations on behalf of environmentalists, with EDF personnel representing both organizations.

III. THE STORY OF THE "SECOND DCMINC": ALDRIN, DIELDRIN AND THEIR FALL

The following account of technical and procedural details of this administrative decision should not obscure a fundamental political fact; the A/D case was a symbolic incident in a highly emotional conflict between agricultural and environmental values. Eminent scientists, among others, exhibited anything but scientific detachment. For example, Nobel Laureate Norman E. Borlaug, father of the "green revolution" in agriculture, decried the "fear-provoking, irresponsible environmentalists" he saw enlisted in a "vicious, hysterical propaganda campaign against agricultural chemicals." "DDT," Borlaug warned, "is only the first of the dominoes...."12 For many on both sides of the controversy, A/D was the second domino.

A. The Chemicals and Their Distribution

1. Production and Sales

Aldrin and dieldrin, like DDT, are persistent chlorinated hydrocarbons, were developed in the middle 1940s, and are stored (as dieldrin) in animal body fat. First registered by USDA in 1949, A/D were produced in the U.S. solely by Shell from 1952 to 1975. The compounds are members of the cyclodiene subclass of chlorinated hydrocarbon insecticides, which also includes the imperiled heptachlor and chlordane (for which most registrations have been suspended by EPA) and endrin (now under serious

consideration for restriction). Aldrin is transformed to the more persistent dieldrin through epoxidation both in the environment and in the body.

For many years Shell sold only high priority "technical" grade A/D to other firms which then formulated ready-to-use insecticide products for sale to retailers under their own brand names. By 1972, however, nearly 90 percent of A/D was sold as formulated product under the Shell label.¹³ Still, at the time of cancellation EPA estimated that valid registrations were held by 377 firms for about 1300 A/D products.¹⁴

In volume of use, A/D ranked sixth among insecticides in 1972 at about 11 million pounds per year; among agricultural insecticides, aldrin ranked fourth.¹⁵ The chemicals had been registered for a broad spectrum of uses; at one time dieldrin was registered for the control of 154 insects, and aldrin for 76 insects.¹⁶ In 1970 dieldrin was registered for use on 80 different crops, and aldrin on 60.¹⁷

Due to the spread of insect resistance and the rise of public concern about the persistent pesticides, A/D sales in the early 1970's had declined from a 1966 peak of 22 million pounds to half that amount.¹⁸ Total sales of A/D in the early 1970's can be estimated at slightly over \$10 million per year.¹⁹ Aldrin was produced exclusively in Shell's Denver plant, which employed 80 persons in its last years of production.²⁰

Aldrin's early use was primarily on cotton, but the boll weevil became resistant in the 1950's and use on soil insects attacking corn then became the predominant market. As of 1974, the volume of end uses for aldrin were reported by Shell as follows:²¹

Corn soil insects	80%
Termites, other uses	
by pest control firms	14%
Seed protection for rice	3%
Other seed protection	1%
Citrus soil insects	1%
Misc. soil insects	1%
	<u>100%</u>

Dieldrin, which in that year accounted for only 6 percent of the total A/D volume, was used as follows:²²

Termites, other pest control	44%
Foliar insects on fruits	20%
Seed protection	14%
Vegetables	13%
Miscellaneous	9%
	<u>100%</u>

2. Aldrin and Corn Production

For both sides, the key A/D use was the application of aldrin on corn acreage; this use represented the bulk of Shell's market and was seen by EPA as the major source of human exposure and environmental contamination.

About three-quarters of the 5 billion bushel U.S. corn crop is grown in the eight midwestern "Corn Belt" states. The leading states are Iowa and Illinois, which each account for about 20 percent of the country's harvest and where one farm acre in three is devoted to corn.²³ Soil insects are hardly the corn farmer's only worry; according to USDA estimates, total yield losses from soil and foliar insect attack (12 percent) have been nearly matched both by plant disease (12 percent) and by weed losses (10 percent).²⁴ Pesticide expenditures amount to but 6 percent of a corn farmer's total costs, rather less than the 13 percent he spends for fertilizer;²⁵ furthermore, less than one-fifth of the farmer's pesticide expenditures are for control of insects, the bulk being spent on herbicides.²⁶ Despite these modest proportions, the magnitude of the national corn crop makes the corn insecticide market relatively attractive. Only the cotton crop, with 33 percent of the total agricultural insecticide market, currently stands ahead of the corn sector, which claims 22 percent.²⁷

In the 1970's aldrin was used only against soil insects in corn. Registrations for use against foliar insects had been withdrawn in 1966, when restrictions on allowable A/D residues in food and feed were tightened. It was used on about 28 percent of the corn acreage treated for soil insects in 1971, and was the clear competitive leader for soil insect control.²⁸ Its popularity was due both to its low cost and its persistence, which enabled farmers season-long protection from a single soil treatment. Aldrin's market share was, however, steadily slipping; twice as many acres had received aldrin only five years earlier, and only 8 to 10 percent of all corn acreage was treated with aldrin in the early 1970's.²⁹ In addition to insect resistance, A/D was meeting resistance by governments; concern about dieldrin residues in dairy products and crops led Wisconsin to ban its use on corn in 1970,³⁰ and the University of

Illinois College of Agriculture stopped recommending aldrin for any agricultural use in the same year.³¹

Of the six insects designated in a recent NAS pesticide survey report as "primary" problems for corn production, aldrin was used extensively against the three soil insects listed: rootworms, wireworms and cutworms.³² An earlier USDA survey of corn farmers found that of corn acres treated with aldrin, 63 percent were treated for rootworm control, 16 percent for wireworms, and 27 percent for cutworms.³³

Although this pattern implies that the rootworm is perceived by the corn grower as the main villain, that pest did not occupy center stage in the A/D proceeding; the rootworm, as Shell acknowledged, had become resistant to aldrin's toxic effects in at least two-thirds of the Corn Belt.³⁴ In addition, acceptable alternative insecticides are readily available for rootworm control. Furthermore, since rootworm damage is encountered primarily in fields where corn is planted continuously, control can be attained by crop rotation.

Similarly, the wireworm (for which resistance to chlorinated hydrocarbons is also suspected by some experts³⁵) is vulnerable to other insecticides. Wireworm infestation occurs mainly where corn is planted following grass, so a corn-soybean rotation or continuous corn production offers protection. In any event, reports of wireworm infestation are relatively infrequent, and Judge Perlman was ultimately led to write that, all things considered, "we are not overly impressed with the importance of the wireworm."³⁶

The black cutworm, however, turned out to be a vexing problem for policy makers; Shell's case spotlighted this insect, and Perlman, who was to later call the prospect of cutworm damage the "most difficult issue in the risk-benefit analysis,"³⁷ worried that the suspension of A/D "imposed some onerous burdens" on farmers with cutworm damage.³⁸ One difficulty was that (except for the other chlorinated hydrocarbons heptachlor, chlordane, and toxaphene) no comparable chemical was readily available for preventive application during planting. Without aldrin a farmer would be required to (a) conduct time-consuming field inspections for cutworm presence, and (b) then apply a more expensive bait or spray formulation, by which time some damage would have occurred. The extent of cutworm damage in the absence of preventive treatment is not well understood. It is known that cutworm damage cannot be eliminated by crop rotation, and that low-lying areas subject to flooding are particularly vulnerable; crop losses up to 15 percent in high risk areas have been predicted by a senior University of Missouri entomologist and Shell witness.³⁹

3. Dieldrin and the Environment

a. Toxicity. Although toxic, dieldrin does not appear to represent a serious danger of acute poisoning in humans; for example, one investigation of 263 reported accidental pesticide deaths in two years revealed only two fatal incidents attributable to A/D,⁴⁰ and an extensive study of Shell plant workers failed to show toxic effects of consequence even from prolonged exposure to levels 175 times higher than average population intake.⁴¹ Agency lawyers did cite reports suggesting sublethal effects of long-term exposure of possible significance to human health (least notably, perhaps, "Derbyshire Droop," the onset of impotence reported in five English farm workers exposed to unspecified amounts of dieldrin),⁴² including libido and reproductive effects in dogs, inhibition of the sex hormone testosterone in rodents, and neurological and behavioral disorders in primates. Rodent studies also indicated A/D was a suspect teratogen.

For lower species, the case is clearer. Among the major chlorinated hydrocarbon insecticides, A/D is second only to endrin in relative acute toxicity.⁴³ Some major kills in the 1950's were attributed to A/D, one application in a Florida marsh virtually exterminating one million fish of 30 different species.⁴⁴ Some fish display toxic reactions at 2-3 parts per billion (ppb), and oysters are affected at less than 1 part per million (ppm), a level that killed 100 percent of exposed quail chicks.⁴⁵ As with DDT, eggshell thinning in birds has been attributed to small body burdens of dieldrin, and allegations of predator losses include one estimate that 10 percent of all bald eagle deaths are due to A/D.⁴⁶ Shell maintained, however, that problems of gross environmental contamination had been solved well before the hearings by the termination of hazardous application practices (e.g., aquatic uses, aerial spraying).

Except for carcinogenicity, neither human nor animal toxicity was crucial to the A/D decision; in fact, some question the trial staff's decision to include these issues in the cancellation hearing. The hearing was punctuated by industry derision of the "everything-but-the-kitchen-sink" approach used in presenting EPA's case.

b. Persistence. Studies show that one year after application, about 25 percent of aldrin remains in the soil in the form of dieldrin. The fate of the rest is imperfectly understood. The half-life of dieldrin in the soil is about four years,⁴⁷ varying with soil conditions from two to seven years.⁴⁸

c. Environmental Pathways. By the time of the A/D cancellation hearing, the key question was the consequence of direct application to the soil. Generally, Shell

discounted the possibility of human exposure due to soil uses, and suggested that careless handling by some A/D formulators was a major source of A/D in the general environment. The EPA trial staff contended that soil application itself led to widespread contamination.

Leaching of A/D is prevented by the chemicals' strong sorption to soil particles. Groundwater contamination, then, is not a major danger;⁴⁹ this fact was a basis for the June 1972 decision allowing continued A/D registration for deep soil insertion to provide long-term termite control around buildings. Three other environmental routes (volatilization and air transport, water runoff, and food plant uptake) caused more concern. A/D is known to volatilize in field conditions; the EPA suspension brief asserted that as much as 1/3 of the dieldrin content of the soybean (itself "probably the most important route" of human exposure) is from foliar sorption of A/D vapor by soybeans grown in fields where A/D had been previously applied for corn insect control.⁵⁰ In addition, transport of dust particles containing A/D may be a problem; dieldrin was found in measurable quantities in 85 percent of EPA air samples taken from 1970 to 1972,⁵¹ average household dust levels of 2 ppm have been observed,⁵² and traces of dieldrin have been detected in rainwater.⁵³

River samples contain dieldrin more frequently than any other insecticide.⁵⁴ The EPA trial staff suggested that surface water contamination, presumably due to agricultural runoff, explains why in recent years FDA Market Basket analyses have reported increasing levels of dieldrin in fish products.⁵⁵

Contamination of crops planted in fields previously treated with aldrin is perhaps the most significant pathway, for this route can lead to human exposure to dieldrin residues in meat and dairy products when feed crops are involved. Soybeans, increasingly rotated with corn to control rootworm, absorb aldrin through the roots, and the resulting dieldrin is translocated to the beans. Average levels of 10 ppb are found in Corn Belt soybeans,⁵⁶ and one recent study found dieldrin in 56 percent of Midwest soybean samples.⁵⁷

d. Human Exposure. Only 1 or 2 Americans in 100 are dieldrin-free. Average dieldrin levels in human adipose tissue samples ranged from .20 ppm to .28 ppm between 1970 and 1974.⁵⁸ The EPA trial staff claimed that since these body burdens are fairly close to levels that have tumorigenic effects in rodents, no margin of safety exists.⁵⁹ The fact that A/D and DDT (also present in most Americans' tissue) have synergistic toxicological effects in mice is further cause for concern.⁶⁰

Known linear relationships (derived from a human feeding study) between rates of intake and storage in body fat imply that in 1972 Americans have been taking in about 13 micrograms a day of A/D.⁶¹ The origin of this dosage is not well understood. Food is one source; recent FDA Market Basket studies found dieldrin in 29 of 30 meat samples, 26 of 30 dairy product samples, and 22 of 30 samples of vegetables.⁶² However, the levels detected would account for less than 5 micrograms daily.⁶³ Dieldrin traces also have been found in 117 of 689 samples of drinking water.⁶⁴ Inhalation of airborne A/D has been suggested as another exposure route; in fact, Shell representatives suspect that termite control use, exempted from cancellation, is today a significant source of volatilized A/D.

B. Chronology

1. Prelude to the Cancellation Notice of 1971

A charter member of the new generation of synthetic organic pesticides, A/D was discovered and developed at about the time that the 1947 FIFRA was enacted. Shell Chemical Company became the sole national distributor of the new insecticide in 1950, and, after amalgamation with the developer two years later, the only U.S. manufacturer.⁶⁵ The 1950's brought nearly unbridled commercial success. Aldrin provided dramatic relief to cotton farmers and later to corn growers plagued by insects; application of aldrin against the corn rootworm commonly returned three or four dollars for every dollar invested.⁶⁶ In 1959 the number of registered uses reached its zenith. Aldrin and dieldrin were registered for use on 91 and 94 crops, respectively.⁶⁷

Nature, technology, and Rachel Carson combined in the early 1960's to dim the miracle that chemical science had created, and by 1970 Shell had voluntarily withdrawn registrations for 150 uses of A/D.⁶⁸ Nature provided insect resistance: first in the cotton boll weevil, housefly, and mosquito, and then the corn rootworm. Technology provided more sensitive devices to measure pesticide residues, thus driving detectable residues to lower levels and revealing the impracticality of some of the established A/D tolerances (allowable residues) for food and feed crops. Public response to Rachel Carson's Silent Spring⁶⁹ helped instigate the series of major policy reviews that provided much of the data on carcinogenesis ultimately used as the basis for suspension.

Silent Spring itself did not spotlight A/D, and while the author made a prescient case for indictment of pesticides as potential carcinogens, the attention given to A/D was entirely devoted to acute toxicity. In a chapter entitled "Elixirs of Death," human body burdens of dieldrin

were said to "lie dormant like a slumbering volcano, only to flare up in period of physiological stress when the body draws upon its fat reserves."⁷⁰ Aldrin was termed a "mysterious substance" because it degrades to dieldrin and thus escapes residue detection.⁷¹ The book's effect on A/D was indirect; it engendered popular concern about DDT, and to some extent environmentalists considered A/E guilty by chemical association.

The first policy review was Use of Pesticides, released by the President's Science Advisory Committee (PSAC) in 1963. This evaluation, containing the pithy policy statement, "elimination of the use of persistent toxic pesticides should be the goal,"⁷² recommended fresh re-examination of several FDA pesticide tolerances by an NAS-appointed committee. Aldrin and dieldrin were two of seven pesticides cited as particularly needing review. PSAC noted with concern that a 1962 FDA animal feeding study using the "C3H" mouse strain had produced liver damage and the induction of tumors (reported as benign) at low (10 ppm) dietary concentrations.

An FDA advisory committee, the Popper Committee, reported on dieldrin in 1965. It recommended reductions in many tolerances, and, having reviewed two mouse studies and two rat studies, declared the case for carcinogenicity "inconclusive" because the study protocols were substandard.⁷³ It recommended new long-term animal studies, which Shell then undertook. In view of the reduced tolerances, Shell withdrew over 60 A/D registrations in 1966, including foliar application to corn.⁷⁴ Many more registrations were cancelled by USDA (without opposition) for the same reason during the next four years.

In June 1968, the Shell animal studies recommended by the Popper Committee were completed and results were transmitted to FDA; this unpublished work, using the "CF1" strain, was eventually to provide the first clear indication of induction of malignant tumors in mouse livers.

The Environmental Defense Fund already had placed A/D high on its suspect list during this period. In fact, a week after its incorporation, EDF took legal action in Michigan against aldrin as well as the better known DDT.⁷⁵ In 1968, EDF petitioned the FDA to reduce all A/D tolerances to zero. FDA declined.⁷⁶

In April 1969, following the well-publicized FDA seizure of 14 tons of DDT-contaminated coho salmon in Lake Michigan, HEW Secretary Finch ordered a comprehensive review of pesticides and health. The recommendations of the resulting Mark Committee report, released in December 1969, contained more bad news for supporters of aldrin and dieldrin.

-- A/D were among 10 chemicals that should be restricted to essential uses.⁷⁷

-- A/D were among 19 chemicals for which animal screening studies indicate a need for (a) minimizing human exposure and (b) additional testing.⁷⁸

-- A/D were among 13 chemicals judged "positive" for tumor induction. This assessment was based on the 1962 FDA study data; although the company indicates that it transmitted its findings to Committee personnel, the later Shell study was not cited.⁷⁹ Furthermore, the Committee's Panel on Carcinogenicity judged tumorigenicity as an appropriate index of potential carcinogenicity.

In March 1970, citing the Mrak report recommendations, USDA cancelled nonessential uses of A/D, including application in aquatic environments.⁸⁰ Two months later USDA, under pressure from environmentalists, noted that aldrin was still registered for 60 crops and dieldrin for 80 crops, and solicited public comments on "which, if any," A/D uses were essential.⁸¹ A six-member advisory group of independent scientists reviewed A/D uses and offered these recommendations:⁸²

-- Corn - discontinue use except for "first-year" corn, for which no adequate substitutes are available.

-- Citrus - continue use against Fuller's rose beetle, because no substitutes are available.

-- Termites - continue use, as no environmental hazard from deep soil application is seen.

-- Seed Protection - continue use, as volume used is very small.

The group recommended termination of all other A/D uses. The corn recommendation precluded use against the pervasive rootworm, which affects continuous corn acreage, but it implicitly left a rather large loophole; only about 50 percent of the corn harvest then came from continuous corn plantings.

EPA came into existence on December 2, 1970. On December 3, EDF filed a petition to cancel and suspend all uses of A/D on the basis that both cause environmental damage and are carcinogenic. The following day William Ruckelshaus was sworn in as EPA Administrator.

A month later the Agency received the USDA A/D review group's report and, according to a later account, was conducting a review of the relevant scientific literature.⁸³ That month the Agency also received the D.C. Circuit Court's DDT decision, which directed the Administrator to initiate cancellation actions against DDT and, if possible, to develop general standards to govern the cancellation of other chemicals. The Court, agreeing with EDF's case against USDA's refusal to cancel DDT, indicated that a cancellation notice was required by FIFRA whenever a "substantial question of safety" was raised for a registered product.⁸⁴

2. Preparation for Cancellation Hearings: March 1971 to August 1973

EPA's handling of A/D took place in the distinct shadow of the DDT proceeding. The emotional climate of DDT decisions effectively relegated A/D to the sidelines until Administrator Ruckelshaus cancelled most DDT uses in June 1972. One result was that the question of cancer risk to humans only slowly emerged from eclipse by a preoccupation with A/D's ecological effects.

In March 1971, EPA responded to the EDF petition by issuing notice that all A/D registrations would be cancelled in 30 days.⁸⁵ In an explanatory statement covering actions for DDT and 2,4,5-T as well as A/D, the Administrator announced that he would not suspend the registration of A/D. No "imminent hazard" was presented, he declared, because:

-- Remaining A/D uses were primarily for ground insertion, "which presents little foreseeable damage from general environmental mobility."

-- There was a pattern of declining gross use.

-- Historical use volume was "lower" [than for DDT and 2,4,5-T, by inference].⁸⁶

In discussing the basis for the cancellation notice, Ruckelshaus elaborated on environmental effects. Cancer risk was treated in a single sentence: "There are also similar carcinogenic data developed in the laboratory from high doses of dieldrin administered to test animals."⁸⁷ The data source was not explicitly cited, but an EPA official indicates that the 1962 FDA finding of tumorigenicity in mice is the likely origin.⁸⁸ The sentence effectively equates tumorigenesis and carcinogenesis. No discussion of specific A/D uses, or of the possibility of regulating some uses and ignoring others, was presented. The reader was generally led to see A/D as a somewhat less hazardous version of DDT. The treatment of A/D leaves doubt that EPA

would have added the insecticides to its agenda at that point if EDF had not petitioned the Agency.

EDF appealed the Administrator's decision not to suspend A/D to the D.C. Circuit. The group argued that cancer risk did represent imminent hazard and that, according to the earlier DDT appellate decision, EPA should be compelled to show that there was at least some benefit to weigh against the risks of continued A/D use. Meanwhile, 84 A/D registrants took advantage of the provision in the old FIFRA specifying that, when requested, cancellation issues must be referred to an advisory committee of individuals nominated by NAS. Cancellation could not become effective until the Administrator had received the group's 60-day study report and action recommendations.

The O'Brien Committee, seven research scientists from non-profit institutions, conducted a literature review and met with several USDA and industry spokesmen as well as a lone environmentalist, EDF founder Charles Wurster. EPA, somewhat suspicious of pro-pesticide bias among the NAS nominees, did little to inform or cultivate the Committee. In fact, some observers feel that the Agency operated on the self-fulfilling projection that the O'Brien panel's findings would prove unsatisfactory.

The O'Brien advisory report was issued in late March 1972.⁸⁹ The keynote sentence of its conclusion was, "We find no evidence of human injury from past or present use of aldrin or dieldrin."⁹⁰ Its recommendations stressed the need for additional empirical study in three particular areas: 1) animal studies on carcinogenicity, 2) the consequence of cancellation in the agricultural economy, and 3) the rate of escape of aldrin from the soil by volatilization. The Committee recommended A/D cancellation for all major uses except soil insect control, seed protection, termite control, and the protective dipping of non-food crops.

The first exception would, of course, allow continued use for both corn and citrus; together with termite control, these applications accounted for about 92 percent of A/D sales in 1971.⁹¹ The report itself, however, gave no indication of the relative economic or ecological importance of the various A/D end uses. The recommendations, it may be noted, are rather less restrictive than those of the earlier USDA review group, which had cleared use on corn only for first-year fields.

Although the advisory report conveyed concern about A/D mobility through volatilization, it was silent on other routes of human exposure from soil application, including uptake into crops (the major route of environmental contamination was identified as runoff).

The report's review of data on carcinogenesis, written by Dr. Stephen Sternberg of the Sloan-Kettering Institute for Cancer Research (later a Shell witness), is somewhat puzzling. It refers to the unpublished Shell work showing induction of liver nodules in the CF1 mouse that were "probably...carcinoma" as the single indication of carcinogenesis.⁹² No reference is made to the published FDA study showing incidence of tumors (then judged benign) in C3H mice, the paper that had caused such concern for PSAC in 1963 the Mrak Commission Panel in 1969. Evidently (the matter is not discussed), Sternberg and the advisory group differed with the Mrak Panel's contention that all tumors, benign as well as malignant, should trigger caution. "If there is a carcinogenic action in dieldrin," Sternberg summarizes, "it is likely a weak one at a level much like DDT."⁹³ The report's summary section states:

...one cannot dismiss the possibility that sufficient doses of dieldrin could be carcinogenic in man, but the degree of uncertainty is inadequate to require prompt elimination from the diet.⁹⁴

These words make the panel's policy preference quite clear, but there is no qualitative or quantitative analysis of what would represent an "adequate degree of uncertainty" to restrict A/D. The lack of such analysis convinced critics that the group's assessment was more a value judgment than a scientific inference.

In early May the Appeals Court handed down its decision on the EDF challenge to Ruckelshaus' refusal to suspend, remanding the case to EPA.⁹⁵ The Court was disturbed by the Administrator's cursory treatment of the cancer question:

...candor compels us to say that when the matter involved is as sensitive and fright-laden as cancer, even a court scrupulous to the point of punctilio in deference to administrative latitude is beset with concern when the cross-reference is so abbreviated.⁹⁶

Within days of his June 14 decision to cancel DDT, the Administrator responded to the court and (as required by FIFRA) to the O'Brien advisory report. He requested public comment on the suspension question and reaffirmed his determination to cancel A/D, but now exempted three registrations; those for termites, dipping of non-food crops (both uses exonerated by the advisory group) and closed-system mothproofing techniques.⁹⁷ He rejected the advisory group's recommendation for continued soil application, however, saying that "widespread ground application results in large amounts of the chemicals escaping from the point of application and threatening harm to the atmosphere and wildlife."⁹⁸ Thus, the hazard was evidently still perceived

in 1972 as ecological damage from volatilization and runoff, rather than human cancer risk via crop uptake.

Shell then played the next procedural card dealt by FIFRA, the right to request a full public hearing prior to cancellation. EDF, USDA, 38 other A/D suppliers, Florida Citrus Mutual (an association of citrus growers), and the American Farm Bureau were among those who petitioned to intervene, and all began earnest preparation for trial.

In early October 1972, EPA distributed responsibility for preparing its case, giving day-to-day management authority to John Kolojeski of the General Counsel's office. Four teams were organized; Human Safety, Environmental Effects, Chemistry, and Benefits. Each team had an attorney and appropriate scientific specialists from the Office of Pesticide Programs (OPP). Kolojeski himself was on the Human Safety team. For the next several months, the litigation team labored to assemble the factual basis of its case.

The Agency's fact-finding efforts were not unimpressive in scope. Ample resources were made available to the litigation team. In part, this generosity reflected the hope that EPA's case on A/D would prove superior to the DDT effort just completed, which many in EPA felt had been unimpressive. Among the critics of EPA's factual case against DDT were many scientists who felt that emotion had been allowed to rule reason; in fact, NAS President Philip Handler was later reported to have characterized the cancellation as "a kind of national scandal" motivated by political factors."

The A/D research effort was, for the most part, the active solicitation of expert opinion. EPA lawyers met informally with a number of experts on carcinogenicity. A consultant, Dr. Melvin Reuber of the University of Maryland, (later a key EPA witness) conducted reviews of the original slides from animal studies, and fresh statistical analysis was also performed. State-level entomologists were surveyed regarding corn cropping practices and insecticide usage patterns in the Corn Belt.

Shell recalls that it made every possible effort to cooperate with the EPA fact finders. Information on sales volume and confidential estimates of A/D's end uses were released to the Agency. The company encouraged the visits Kolojeski and others made to its California offices and its research laboratory in England.

Among the most difficult tasks facing the Agency was the compilation of empirical evidence on corn insecticide use. Entomology is an extremely complicated science, one in which widely varying field conditions seldom permit simple

generalizations. Insect behavior, as well as the specific insecticidal action of chemical compounds, vary with any number of climatological and agronomic factors and with agricultural practices. The application of insecticides in particular instances is less a matter of scientific farming than trial-and-error experience. The end result is that definitive knowledge is rare, and the best subjective judgment of entomologists is often the best empirical "data" available.

Consequently, the litigation team had difficulty with the assessment of the benefits of A/D use. The problem was exacerbated by tension between OGC lawyers and entomologists and economists in OPP who were analyzing benefits. Ultimately, the initial OPP benefits analysis was buried and a second effort was begun under closer OGC supervision. The lawyers were distrustful of the conclusions of the entomologists whom OPP had consulted on such issues as the relative effectiveness of A/D and competing products and the extent of actual insect damage in treated and untreated fields. As a professional field, the lawyers maintained, entomology is dominated by pesticide firms; much research, including that at universities, is funded by chemical firms, a fact that OGC lawyers felt complicated their search for unbiased expertise. In addition, the attorneys surmised that Shell must have known more about field use of A/D than it let on. Specifically, there was suspicion that A/D had been oversold to farmers as cheap, carefree protection against the vaguely-defined "soil insect complex"; upon closer scrutiny, A/D was found effective against only two economically significant insects, the cutworm and wireworm.

A small number of new empirical studies were set in motion at the instance of the EPA trial staff, including mutagenicity and teratogenicity studies. Neither produced positive results (although positive findings in another teratology study were introduced as evidence). Another animal study, involving a two-year feeding study on mice, rats, and hamsters, was advocated by OGC, but OPP considered support of this research effort infeasible (the proposed investigator was Reuber).

Concurrent with the litigation team's fact-finding effort was a series of meetings, authorized by Kolojeski, between OPP scientists and Shell representatives. Terms of a negotiated settlement were discussed. The pesticide firm's willingness to accept a future moratorium on corn use surfaced early in the exploratory talks.

In December 1972, Ruckelshaus again decided against suspension.¹⁰⁰ One reason that suspension was unnecessary, he said, was that several ecologically hazardous A/D uses had been voluntarily withdrawn, including aerial applications, dust formulations, and use against fire ants.

The economic significance of these practices was not indicated, but could not have been large. The Administrator said that the only evidence of carcinogenesis came from Shell's CF1 mouse study, evidence that represents "a caution signal as to long-term exposure, but does not amount to a red light requiring immediate elimination" of A/D.¹⁰¹ He appears to have overlooked (as had the O'Brien Committee) the 1962 findings of tumorigenicity in the C3H mouse. These tumors were still considered benign (the conflicting Reuber review was still a year in the future), but Ruckelshaus himself had explicitly equated tumorigenicity and carcinogenicity for policy purposes in his DDT decision six months earlier.

In January 1973, available evidence on the carcinogenicity of A/D was reviewed at an informal meeting with public officials and private parties at NCI. EPA's attorneys sought expert comment on the strength of their human cancer case and the interpretation of available animal test results. The assembled cancer experts indicated that the case was sound. In retrospect, the trial staff was to consider this meeting a major milestone in the case. Cancer became the central issue in the A/D proceeding, which was henceforth transformed from a DDT-type review of environmental damage into a precedent-setting attempt to control a potential human health hazard. Later that year Shell complained that the NCI session amounted to a "secret advisory committee" and unsuccessfully requested reactivation of the O'Brien committee to once more advise EPA on questions of human toxicology.¹⁰²

Meanwhile, settlement negotiations continued. In February, Shell offered to restrict A/D use on corn through label changes that would (a) delete directions for rootworm control, and (b) specify use only on first-year corn or on fields with past history of infestation by cutworms, wireworms or white grubs.¹⁰³ The reduction in use volume and environmental contamination that this measure would achieve was not estimated; a key question was whether farmers would persist in using A/D against their number one soil insect enemy (rootworm) despite the label changes. Feeling they had fashioned a reasonable compromise, the OPP scientists retired and the trial attorneys carried the settlement talks forward.

EDF and EPA attorneys asserted that no settlement that allowed for indefinite use of a potential carcinogen would be acceptable. Shell subsequently offered to include a September 1976 cut-off date for all contested A/D uses. The company also expressed willingness to meet a new EPA/EDF demand that it endorse a set of stipulated facts on the toxicology of A/D. The proposal was weighed by senior EPA officials. An advantage of such a settlement, cited by trial attorneys, was that it would liberate Agency resources

for the cancellation of heptachlor and chlordane, by then clearly perceived as the next cancellation targets. The Agency's counterproposal was a consent order that called for A/D termination in September 1975 and included a statement of facts relating to carcinogenicity, one of which was an inference of potential human risk. Some industry representatives suspect that this demand was deliberately designed to be unacceptable, and that negotiations had been kept open merely to give EPA trial attorneys additional time to prepare their case. EPA attorneys discount this proposition.

In any event, no settlement was reached. The company indicated that it could not sign a statement that its product may be a human carcinogen. The Agency seems to have stiffened its terms at a point when a compromise seemed near that would be acceptable to all parties, including EDF. The Agency's shift was influenced by apprehension that an informal private agreement (especially one that countenanced continued use of an alleged carcinogen) would not make favorable press for a young Agency nurturing a public image of openness and toughness with polluters. Less prominent was the argument that a decisive adjudicatory victory on A/D would establish a valuable precedent for actions on other chemicals.

The feeling that the A/D case was being pressed for political reasons, despite their best efforts at a reasonable settlement, alienated many OPP scientists. Tension grew, culminating in what amounted to a formal protest to the trial staff's draft pre-trial brief of April 1973. The protesting memo to Kolojeski criticized the extreme position adopted in the brief and said:

...your case is based in part on the claim that no benefit will justify the risk of cancer.... For EPA to officially state such a position, even if it is overturned, is setting a dangerous precedent that we as scientists cannot condone.¹⁰⁴

3. Cancellation Hearings and Pressure for Suspension

The formal cancellation hearings opened on August 7, 1973, nearly 2 1/2 years after the original cancellation notice.

The first two months were spent in field hearings in several agricultural locations. Testimony was taken from over 120 farmers on their need for aldrin. Many stated that alternative chemicals were less effective than aldrin or gave no protection at all.

EPA and EDF then presented their case on the environmental effects of A/D. Thirty-six witnesses appeared during 26 hearing days. For the next three months, the Agency put forth its evidence on the human health effects of A/D, including cancer. Ranking officials from NCI and FDA testified. Cross-examination was extensive, particularly in the case of EPA witness Reuber. Reuber's interpretations of the 20-year old FDA rat study (EPA's strongest evidence for carcinogenesis outside the mouse liver) were heatedly controverted. EPA concluded its case on March 22 after presenting several entomologists who testified that A/D substitutes were available.

USDA opened the A/D proponents' case by presenting evidence for three weeks on the need for A/D for uses not contested by Shell (the manufacturer defended only uses against corn and citrus soil insects and for seed protection). Shell then presented 22 witnesses on environmental effects. The firm was midway through its case on the benefits of A/D when, as described below, the Administrator issued his August 2 suspension notice and the cancellation hearings halted. The company had not yet begun its human health case, which, inferring from lists of witnesses to be called, would have been extensive. Some Shell officials suggest that the real intent of suspension was to foreclose anticipated damage to EPA's cancer case. Shell counsel called the mid-case suspension a "procedural nightmare."¹⁰⁵

The cancellation hearing had produced 249 witnesses, 24,000 pages of transcript, and 950 exhibits comprising another 11,000 pages.¹⁰⁶

The main drama of 1974 took place outside the hearings rooms. In early March, USDA inspectors had found widespread dieldrin contamination in Mississippi chickens, and 7.6 million birds were gassed and buried.¹⁰⁷ The prevailing theory was that these chickens had eaten feed supplemented with industrial grade vegetable oil. Soybean oil is produced by distillation, which concentrates pesticides and other contaminants in a residue that, while rich in nutrients, is not to be used in food or feed. Some is occasionally diverted, however, and the Mississippi chicken episode aroused public awareness of the feed-to-food route of human contamination.

The media covered the incident fully, and, amid clamorous public reaction, EPA moved to introduce new evidence on A/D hazards to supplement the case it had concluded two weeks earlier. Almost simultaneously, EPA General Counsel Kirk advised Shell that the Agency was, for a third time, actively considering suspension. He asked the manufacturer to voluntarily forego A/D production in 1974.¹⁰⁸ On April 16, Shell attorneys replied that the

company would not comply. EPA desisted. One published account asserted that the Agency lost its appetite for suspension when it discerned the angry opposition of Congressman Jamie Whitten, whose House Appropriations Subcommittee was then reviewing EPA's budget.¹⁰⁹

Outside pressures mounted during the summer months. It was expected that Shell would begin production for the 1975 crop year in September. Congressmen and the press openly questioned EPA's reluctance to move decisively on A/D. Senator Philip Hart's Subcommittee on the Environment was about to hold August pesticides hearings at which EPA's inaction doubtless would be further castigated. On July 28, the Washington Post printed an article that charged that the Agency's reticence was rooted in crude power politics:

Observers acquainted with EPA's operations attribute the agency's reluctance to order a suspension primarily to its need for an accommodation with Rep. Whitten, though the impeachment crisis is thought to have increased EPA's susceptibility to pressure.... [T]he President's dependence on conservative support has strengthened the hand of rural and agricultural opponents of environmental measures.¹¹⁰

One informed observer¹¹¹ sees this public accusation as the last straw for the embattled OGC; five days later Administrator Train announced the suspension of A/D.¹¹²

4. Suspension

Train, estimating that the taking of evidence in the cancellation proceeding could require four to five more months, said he was compelled to take an action twice rejected by his predecessor because new information had come to his attention. Two types of evidence were adduced: (a) the production and use of A/D had unexpectedly increased in recent years, and that despite earlier actions to reduce contamination, environmental and human body burdens were not declining, and (b) while earlier decisions had been based only on evidence of carcinogenicity in one mouse strain, "evidence now available indicates that dieldrin definitely causes significant increases of tumors in two and probably three different strains of mice."¹¹³ Positive findings in rats were also alleged. Acknowledging that Shell had not yet begun its cancer case, Train stated, "The cancer experts with whom we have consulted advise us that the rebuttal evidence thus far proffered by Shell is unlikely to be persuasive."¹¹⁴

In suspending A/D, the Administrator faced a statutory complication in disposing of A/D products already in

commerce. FEPCA stipulates that when use of a pesticide is banned, EPA is required to indemnify those who already own stocks of the material at a fair market price, presumably paying from Agency funds.¹¹⁵ According to later Congressional testimony by an EDF attorney, EPA estimated existing stocks at roughly 4 percent of annual production and admitted off the record that, if payment of indemnification were required, the Agency's first suspension action would also be its last.¹¹⁶ Train's solution was to permit normal use of existing stocks; this put him in the awkward position of arguing that although another year of A/D use presented imminent hazard (it would add about 3 percent to the cumulative volume of A/D ever used), routine use of a few hundred thousand pounds did not.

Shell, asserting it was stunned by the suspension announcement, requested an expedited hearing on the suspension decision, and all sides raced to prepare arguments. FEPCA does not specify that the ALJ for a cancellation proceeding also preside at the suspension hearing, and while Shell requested that Judge Perlman sit at the new proceeding, EPA considered naming a new arbiter before eventually agreeing on Perlman. Train specified that the expedited suspension hearing should consume no more than 15 hearing days, of which 12 were allotted to Shell because its cancellation case had been truncated. Shell presented 18 witnesses and EPA presented 13 in the suspension hearing. At Perlman's suggestion the EPA trial staff narrowed the issues, arguing for suspension solely on the basis of carcinogenic of risk. Shell emphasized the lack of alternative pest controls for the 1975 season, and asserted that the only cancer threat was to livers of mice.

Nearly half of the record for the cancellation hearing was incorporated into that of the suspension proceeding. By Agency rules of practice, Perlman was given but eight days following the close of arguments to deliver his recommended decision to the Administrator. To his considerable discomfort, he managed to produce 420 column-inches of Federal Register text within the allotted time. His findings almost uniformly accepted the EPA trial staff's case. The only substantial exception was his being "hesitantly unwilling at this time to find that dieldrin is conclusively a carcinogen in the rat...."¹¹⁷ He was also troubled by the plight of corn farmers threatened by cutworms, but nonetheless recommended suspension of this use of A/D.

On October 1, 1974, Train affirmed Perlman's findings in a statement (itself 204 column-inches long) produced in nine working days. Train was less dubious of the rat results, concluding that there is "a strong probability that Aldrin/Dieldrin is a carcinogen in rats as well as mice."¹¹⁸

5. Denouement and End

EDF appealed Train's decision to the D.C. Circuit Court, which had ruled favorably on its earlier suits, protesting EPA's decision to allow use of existing stocks; Shell wanted the Fifth Circuit in New Orleans, which had previously ruled in favor of pesticides, to hear its multi-faceted appeal. Since venue would be determined by filing precedence, both sides held open telephone lines to the respective courts and awaited the formal announcement. Train's decision came at 9:19 a.m. and EDF's appeal was logged in across town at that instant; Shell's filing was somehow registered at 18 minutes after the hour in New Orleans (although the clerk's office officially opened at half past). It was subsequently determined that EDF had won the filing race and that the case would be heard in Washington.¹¹⁹

The appeals case was argued in February 1975. The court's decision, affirming the Administrator's decision in virtually all respects, was handed down on April 4.¹²⁰ The question of the disposition of existing stocks had become largely moot by this point, as EPA surveys of registrants showed steadily declining volumes (less than 4,000 pounds in early April),¹²¹ but that part of the decision was remanded to EPA.

Shortly afterward Shell announced that it would no longer manufacture A/D, even for uses exempted from suspension. EPA then filed a motion for an accelerated cancellation decision, which Judge Perlman issued on May 27.¹²² No objections were filed, and the Administrator's Office declared the decision final on June 30, 1975.¹²³

With suspension, A/D usage on corn declined in 1975 by over half to 3.3 percent of all corn acreage,¹²⁴ but corn farmers still spent over \$6 million on aldrin.¹²⁵ (EPA has since testified that it believed at the time of suspension that indemnification costs would be only \$900,000.)¹²⁶ Heptachlor and chlordane use on corn increased by some 50 percent in 1975, but the total acreage treated with H/C remained under 3 percent.

The market for A/D uses exempted from the cancellation order may be as high as one million pounds (about one-tenth of the precancellation market), according to estimates cited by EPA.¹²⁷ Shell firmly refuses to supply this market, although its A/D production continues overseas, and has indicated that the prospect of liability suits ("several" of which have been instituted) is one weighty deterrent.¹²⁸ A Los Angeles firm expressed willingness to manufacture aldrin in 1976,¹²⁹ but Shell representatives say the California firm has since failed. EPA reports that three pesticide formulating firms now hold registrations for aldrin and six for dieldrin.¹³⁰ Shell, however, holds the only U.S.

registration for technical grade A/D, and has refused all purchase offers from would-be formulators.

IV. THE PREDOMINANT ISSUES: CANCER AND CORN

A. The Carcinogenicity of A/D

1. The Setting

Cancer seems to hold special terror; asked what disease or ailment they fear most, 58 percent of a sample of Americans named cancer, three times the number naming the second-place affliction, blindness.¹³¹ As with many strong aversions, the intensity of this fear is only partly based on fact; cancer ranks behind arterial diseases (heart disease was named by only 10 percent in the attitude survey) both as a cause of death and for average shortening of victims' lives.¹³² Rational or not, however, the grim fear of cancer pervaded and dominated the A/D case. Judge Perlman reflected the mood early in the suspension hearing: "I mean there is no fooling around, the major issue is cancer."¹³³

The cancer issue was debated simultaneously at two levels in the A/D case. The first involved arguments about the degree of human risk of the specific compounds aldrin and dieldrin. The second (treated at length in the companion case history by Karch) concerned general criteria for extrapolation from test results to human risk. To summarize, the EPA trial staff held that there are "established principles of carcinogenicity." Nine such principles were listed in the EPA suspension brief, including, for instance, "even the introduction of benign tumors is sufficient to characterize a chemical as carcinogenic," and "carcinogenicity can be determined through laboratory testing of experimental animals."¹³⁴ EPA's consideration of these broader questions placed the Agency at the leading edge of the slowly emerging national policy for chemical carcinogens.

As to the narrower question, EPA's basic argument was that aldrin and dieldrin had been shown carcinogenic in five strains of mice and, at slightly lower levels of statistical significance, in two strains of rat.¹³⁵ Shell argued that clear proof was available only for the mouse liver and that available human epidemiological studies revealed no adverse effects of long-term A/D exposure.

2. Studies of Man, Monkey, and Dog

Because cancer can have latency periods of more than 20 years, because human experimentation is unthinkable, and

because levels of accidental exposure to suspect carcinogens are rarely known with precision, conclusive evidence on carcinogenicity is rarely found in human studies.

Shell cited two studies that, it claimed, indicated absence of human cancer hazard from prolonged A/D exposure. One was a Danish epidemiological study indicating no relationship between cancer and long-term use of the drug phenobarbital, a substance that produces the same characteristic enzyme induction and subcellular changes in mouse livers that are associated with A/D.¹³⁶ The second was an extensive review of the health of 826 workers at Shell's Pernis production plant in Holland. The workers, who had been exposed to A/D for up to 15 years, suffered only two cases of cancer.¹³⁷

EPA witnesses argued that neither study provided adequate proof of human safety. The worker study was discounted on methodological grounds (EPA suggested that adversely affected workers may have quit or been transferred, and that the worker sample was not representative of the general population). The study was also criticized for examining periods of exposure shorter than the probable latent phase of cancer development (only 35 workers had been exposed for more than 10 years). Judge Perlman was evidently persuaded on this count; "all that can be said with respect to the Pernis experience at this time," he wrote, "is that an excess of cancer has not yet appeared in those workers."¹³⁸

Three experiments with dogs and one with monkeys showed no indication of tumors, although Reuber later discerned hyperplasia in dogs. They were reviewed by three EPA scientific witnesses and dismissed as inadequate cancer tests, primarily because none met the criterion of lifespan study.¹³⁹ The ALJ and Administrator both accepted the trial staff's argument.

3. Mouse Studies

Shell did not dispute the question of mouse liver carcinogenesis in the EPA hearings; its argument was that the effects were unique to the mouse liver. "The mouse liver," said Shell, "is a thing apart."¹⁴⁰

Shell claimed that the mouse's response to A/D involved induction of microsomal enzymes in the liver, followed by liver enlargement through hyperplasia (rapid cell growth) and, ultimately, tumor formation.¹⁴¹ No other species shows the enzyme-hyperplasia linkage, Shell asserted, and enzyme induction is not found in plant workers or monkeys exposed to A/D.

EPA contended that, in fact, proper interpretation of the worker study shows that enzyme induction is demonstrated in humans as well as mice.¹⁴² Dismissing Shell's enzyme theory, EPA advanced quite different claims about cancer development in the mouse liver. The Agency's key witness in this area, Melvin Reuber of the University of Maryland Medical School, testified that mouse liver carcinomas appear after the liver shows areas of hyperplasia and then develops "hyperplastic nodules." These nodules, he asserted, can become cancers, even after exposure to A/D ends; while a pathologist would not find the nodules themselves malignant, he concluded, they should be considered precarcinogenic.¹⁴³

With the exception of the clear finding of a statistically significant increase in spontaneously-occurring types of tumors in a mouse strain (the Shell study in CF1 mice), the EPA case was built entirely on re-examination of organ sections by EPA witnesses; these slides came from studies for which the experimenters themselves concluded that A/D was not carcinogenic. Much of the disagreement was over Reuber's definitions of malignant and normal cell structure and the meaning of the hyperplastic nodule.

Of the mouse studies discussed in the A/D hearings, the earliest were conducted by the FDA using inbred "C3H" mice, presumably in support of the agency's role in setting safe levels for pesticide residues in food. One of these, published in 1962, reported that "benign hepatomas" were found in about 4 percent of the control animals and about 17 percent of animals fed 10 ppm aldrin or dieldrin.¹⁴⁴ This study had caused concern in the 1963 PSAC Report and the FDA advisory committee reviews of 1965 and 1967, and convinced the 1969 Mark Commission to put A/D on its "suspect" list. EPA witnesses later reinterpreted the old FDA slides and concluded that the tumors were malignant and that tumor incidence in treated animals was 82 percent-87 percent.¹⁴⁵

As a result of the recommendations of the PSAC and Popper Committee reviews, Shell had agreed to undertake mouse studies at its Tunstall laboratory in Kent, England. The "CF1" mouse was selected. A contemporary report stated that tests would conclude in June 1967.¹⁴⁶ Shell reported at least partial results to FDA in 1969.¹⁴⁷ While company scientists concluded by 1972 that the observed tumors were malignant, and reported this conclusion to appropriate authorities, the ultimate finding of carcinogenicity was unpublished until 1973.¹⁴⁸

A third study, funded by Shell and conducted at the University of Florida, reported that Swiss-Webster mice developed hyperplastic nodules but no tumors.¹⁴⁹ Pathological review by Reuber indicated that liver cancer

was in evidence, and further review by one of the original authors confirmed Reuber's view.

Positive results for these three mouse strains were claimed in the EPA suspension notice of 1974. In the trial staff's September 1974 suspension brief, the count had swollen to five, a tally accepted by Perlman and Train.

EPA's summary brief also concluded that, according to reanalysis of reported data, significant tumor incidence was found at other sites besides the liver.¹⁵⁰ Shell objected to the statistical procedures EPA witnesses used to arrive at this inference.

4. Rat Studies

Crucial to the cancer cases of both sides, the rat data occasioned some of the most spirited dispute in the A/D case. EPA was eager to demonstrate carcinogenesis in a second species, in light of an informally-held convention that two or three species should show susceptibility before proof of carcinogenesis could be accepted (however, the Administrator later concluded that mouse results alone would suffice, saying that proof in two species "is helpful, but not absolutely essential, to a finding of imminent hazard").¹⁵¹ Shell was, if anything, more dependent on negative findings in the rat, since it claimed that the rat fails to exhibit the microsomal enzyme-liver hyperplasia progression identified in mice. One Shell witness testified that if carcinogenicity were proven in the rat, his odds of A/D being a human carcinogen would be about 70 percent.¹⁵²

Several published studies existed on the rat in 1973; none of them reported that A/D was carcinogenic. Debate over EPA's review of a 1952 FDA rat feeding study published in 1964 was heated.¹⁵³ The original authors had reported some increase in non-liver tumor induction, but the effect was not dose-related; higher dosages produced fewer tumors.¹⁵⁴ EPA consultant Reuber re-examined the 20-year-old slides twice in late 1973, and appeared to reach varying conclusions. Both reviews led him to find evidence of liver cancer. However, Shell thought that his apparently discrepant findings eroded his credibility as a witness.

EPA argued that the FDA study, properly analyzed, showed statistically significant non-liver tumor incidence. In addition, independent analysis by an FDA statistician of a Shell study in a second strain of rat (not histologically reviewed by EPA witnesses) found an incidence of total body tumors just outside (at 5.8 percent) the standard 5 percent confidence interval.¹⁵⁵ Shell argued that no proof of carcinogenicity in the rat had been adduced. As noted

above, ALJ Perlman and Train were less than fully convinced about the rat findings.

B. The Consequences of Growing Corn without Aldrin

1. General Economic Effects

More than 90 percent of the A/D used under registrations cancelled by EPA was applied to control corn soil insects. Citrus uses were also discussed in some detail, but many other minor uses defended by USDA received relatively little analytic attention or rhetoric. EPA personnel were thus spared the necessity of analyzing a large number of minor uses, and neither Shell nor the Appeals Court raised objections to the short cut. Narrowing the issue to corn, however, hardly made it easy to assess the consequences of banning A/D.

Unanswered questions abounded on the central issue, aldrin's effect on corn production. Any analysis of benefits must begin with a description of present A/D uses, and it is at this point that uncertainty begins its reign. There is no clear indication of why corn farmers used aldrin. Environmentalists contend that it was used for general crop insurance, and overused at that, because A/D salesmen overstated its effectiveness. Farmers, in their view, had been persuaded to apply aldrin to the soil during planting for prevention of infestation by any of some 20 members of a "soil insect complex." Slowly it became clear that only three soil insects (rootworm, wireworm, and cutworm) cause damage at economically significant levels. Even that point, according to EPA personnel, was difficult to verify. Entomological witnesses for EPA testified that aldrin use reflected Shell's promotional efforts more than the chemical's relative efficacy; Velsicol Corporation's heptachlor and chlordane, they said, gives equivalent control, but were used less because Shell's sales effort was superior.

The U.S. devotes one-thirtieth of its land area to corn production,¹⁵⁶ and prospective effects on yield from insect damage would have obvious economic significance. Nationally, however, only about 8 percent of corn acreage was treated with aldrin, and three farms out of four used no insecticide on corn.¹⁵⁷ State-to-state variation in aldrin use is large, even for contiguous farmland; Shell data for 1972, for instance, indicated aldrin use on 38 percent of Missouri corn acreage, but only 15 percent in Illinois and Iowa and less than 4 percent in Nebraska.¹⁵⁸ No aldrin at all was used on Wisconsin corn. Because soil insects pervade the Corn Belt, reasons for this wide variation are not immediately evident.

Further confusion appears in the fact that, although over half of aldrin users surveyed by USDA said they were using aldrin against the rootworm, entomologists agree that this insect is resistant to chlorinated hydrocarbon insecticides in most of the Corn Belt. In fact, Shell never contested elimination of the rootworm registration. An explanation is that farmers had no precise idea of which insects they were controlling with aldrin. Some users may not have even known that they were using aldrin; an EPA witness reported that in reviewing incidences of cutworm infestations, 53 of 134 farmers interviewed could not name the insecticide they had applied.¹⁵⁹

The retail cost per pound of aldrin in 1974 was \$2.02.¹⁶⁰ Applied at 1 to 1 1/2 pounds/acre, treatment represented a small part of the average corn farmer's total costs (\$130/acre).¹⁶¹ The costs of aldrin substitutes for rootworm and wireworm control were between \$3 and \$4/acre,¹⁶² but the additional cost was not large in comparison with average profits of \$46/acre.¹⁶³

Estimates of overall effects on yield varied enormously, leading Judge Perlman to the weary observation that "we have been casting about in these proceedings for a reliable estimate of the reduction in yield" if A/D became unavailable.¹⁶⁴ EPA minimized the expected impact. In fact, one Illinois entomologist (and EPA witness) has reported that there is a positive correlation between corn yield and the decline in use of chlorinated hydrocarbons in that state.¹⁶⁵ An earlier study found that the corn borer (which the NAS pesticide review terms a "primary consistent" corn pest¹⁶⁶) increased by 160 percent in areas heavily treated with aldrin, "presumably the result of the destruction of some of the natural enemies of the corn borer."¹⁶⁷

Shell and USDA witnesses foresaw dramatic adverse effects on yield; the highest estimate was about 5 percent of the total corn crop, which, an EPA economist observed, amounted to 100 percent loss for over half the acres now treated with aldrin.¹⁶⁸ EPA's trial staff (and later Perlman) criticized the Shell and USDA witnesses' estimates as unpersuasive because they were based on subjective guesses by selected entomologists.

EPA commissioned a study by a consultant (a former Undersecretary of Agriculture) who analyzed the macroeconomic effects of 1 percent, 2 percent, and 3 percent declines in yield.¹⁶⁹ No significant impact was found. In his decision Train explicitly endorsed Perlman's general summary of the corn question; "we cannot find any major economic or social benefit resulting from the use of aldrin on corn in 1975."¹⁷⁰

A year and a half after the final suspension decision, EPA calculated the economic impact of the cancellation of A/D (jointly with H/C, since uses overlapped considerably); the estimate was roughly \$14 million/year for 7 years, with half of that sum in the corn sector. The Agency could not resist the impulse to explain that this represented a cumulative cost of about 24¢ per capita.¹⁷¹

2. The Cutworm Conundrum

Although decisive about the aggregate economic effects of separating aldrin from corn, EPA decision makers were a bit unsettled about the impact on a particular class of corn farmers.

The bug in this ointment was Agrotis ypsilon - the black cutworm. The nature of its life cycle, it is felt, makes resistance to aldrin unlikely in the U.S., although some resistance has developed in Brazil and Taiwan. Cutworms are not controlled effectively by crop rotation or other cultural practices. They present a tangible threat of heavy and sudden damage; one farmer testified that he lost 50 percent of his crop (400 acres) "overnight."¹⁷² A Shell witness predicted 15 percent losses in affected areas of Missouri in a bad year,¹⁷³ and an EPA witness estimated that, in an epidemic year, up to 2 percent of Illinois' corn acreage could be affected at economic levels (emergency control was required on 1.25 percent of Illinois' corn acreage in 1972).¹⁷⁴

Moreover, EPA had difficulty in specifying an alternative product (other than heptachlor/chlordane) that could give comparable control. Reliance on a less persistent pesticide would require that the farmer monitor his field for cutworm incidence after corn plants had appeared and then, if cutworms were detected, apply a more costly chemical to obtain only partial remedial control. Such procedures represented an unwelcome departure from most farmer's corn-tending habits, and Shell doubted that effective control could be counted on.

EPA strategists gave fleeting thought to making a policy exception for cutworm control. One feasible method would have been to effect a label change restricting use to those areas with actual past cutworm problems. Label directions permitting aldrin use on fields with past cutworm problems were part of a May 1975 settlement proposal offered by OGC. It appears that vulnerable fields can be identified fairly reliably. In a 1975 retrospective study of cutworm incidence, nearly 90 percent of the affected fields were found to be poorly drained, low-lying "bottomland" in which no-till or low-till farming left considerable surface debris.¹⁷⁵

The practical difficulty with such a measure was that it could not be enforced. Although FEPCA prohibits pesticide use "inconsistent with the labelling," EPA has developed no effective means of policing this provision. In the absence of effective enforcement, EPA speculated, farmers might continue to use aldrin widely against rootworm and wireworms, if not for general insurance purposes.

Judge Perlman effectively held his breath ("We do not expect the corn farmer who has cutworm problems to like this conclusion. We have, perhaps, imposed some onerous burdens upon him."¹⁷⁶) and suspended aldrin for cutworm use as well as other contested uses. Administrator Train followed suit. In response to Shell's subsequent argument that post-infestation controls represent an inordinate work burden on the farmer, the appellate court was succinct; "When the subject is risk of cancer, convenience may be relevant but it does not weigh heavy in the scales."¹⁷⁷

EPA's cutworm decision was mitigated to some extent by knowledge that heptachlor and chlordane would be available for the 1975 season. On the eve of the suspension hearing EPA quietly indicated that it would take no action against H/C until the fall production run was completed.¹⁷⁸ It was evident that these chemicals were next in line for cancellation, and the trial staff refrained from offering H/C as acceptable substitutes for A/D in the cancellation phase. In the suspension hearings, however, the decision was ostensibly limited to a single growing season, and the two chemicals would in fact be available, as Perlman emphasized.¹⁷⁹

Shell attacked this point, contending that corn farmers' shift to H/C (also shown to be a carcinogen in a mouse study) would hardly reduce risk to the general public. Here too, the D.C. Appeals Court supported EPA, Judge Leventhal archly noting that "There is no law that says that all evils must be attacked at the same time and the same rate."¹⁸⁰

When, in early 1976, the Agency turned to the suspension of heptachlor/chlordane, the cutworm issue remained a difficult question, and this time no back-up chemical was available. Judge Perlman recommended against suspension of H/C, and the cutworm was clearly on his mind:

We are concerned about...and have agonized over the possible effect of such a suspension upon certain individual farmers. The problems presented by a suspension to the corn farmer of Missouri bottomland, for example, are substantial.¹⁸¹

Although the Administrator reversed the Judge's suspension decision, he did allow corn farmers to use H/C

through the 1976 growing season in order to provide time to learn and adopt alternative cutworm control measures.

V. LESSONS FROM THE CASE FOR EPA DECISION MAKING:
THREE SHORT ESSAYS

A. Deciding What to Decide--The Matter of Priorities

1. The Selection of A/D for Cancellation

EPA's assessment of A/D rested on the implicit assumption that A/D deserved all the attention it received. One might well agree with Judge Leventhal's observation that public policy need not expunge all evils simultaneously and yet feel that something better than mere chance should guide the ordering of evils indicted. Whether A/D should be selected as the second domino is a question that apparently did not receive much attention at EPA.

The decision was effectively made by EDF when it delivered its petition for cancellation and suspension in December 1971. (EDF took concurrent action against 2,4,5-T and mirex, but EPA cancellation of these chemicals was delayed for extraneous reasons.) Given the political climate, it would have been difficult for EPA to have ignored the A/D petition while it indulged in a study of alternative cancellation candidates. In any event, one scientist-administrator doubts that such a review would have reached a different conclusion; "everyone understood that aldrin and dieldrin were next on the list."¹⁸²

Viewed with benefit of hindsight, the choice of A/D does not seem merely arbitrary. In terms of volume used, A/D was third highest among persistent insecticides. Only toxaphene (discussed below) and DDT were better sellers. As for environmental effects, the chlorinated hydrocarbon endrin was far more acutely toxic to animals (and, unlike most other chlorinated hydrocarbons, was also increasing in agricultural use volume, tripling between 1966 and 1971),¹⁸³ but A/D ranked second among major persistent compounds in acute toxicity, and endrin does not bioaccumulate.

If the perceived "evil" is carcinogenicity, the rank-ordering of pesticides becomes highly conjectural. There is no shortage of alternative candidates in this area; lists of from 13 to 63 potentially carcinogenic pesticides have been compiled between 1969 and 1975, and one scientist asserts that, among the chlorinated hydrocarbons alone, 18 of 21 compounds adequately tested in animals have now proven carcinogenic.¹⁸⁴ A plausible way to differentiate potential carcinogens is according to human body burden. Concentrations of dieldrin in human adipose tissue ranked third; they were only about one-half those of benzene

hexachloride (BHC), another chlorinated hydrocarbon insecticide, and about one-fiftieth of those of DDT.¹⁸⁵ (Results reported in 1977 are similar.)¹⁸⁶ BHC, therefore, might have been a logical choice for cancellation in 1971. In fact, in October 1976 the Agency announced its intended cancellation of products containing BHC because of carcinogenesis. EPA now notes that the compound had proven carcinogenic in seven strains of mice in studies published between 1971 and 1975, and that test data for rats also look suspicious.¹⁸⁷ All that seems to have distinguished BHC from A/D as a cancer suspect in 1970 is that it had not been as fully studied (lacking even initial carcinogenicity data, the Mraz Commission did not nominate BHC--or toxaphene--for further feeding studies in its 1969 report).

Body burden does not translate directly to human cancer risk, however. Some EPA and FDA scientists were convinced that, based on animal studies then available, the metabolites of heptachlor and chlordane were "more carcinogenic" than dieldrin, despite their lower concentration of H/C in human tissues.¹⁸⁸ (90 percent tumor incidence had been found in a 1967 H/C mouse study, five times the reported incidence for A/D). If accurate, this reasoning implied that the cancellation of A/D would lead to increased human risk to the extent that H/C was substituted for A/D.

This point was not lost on Shell, which believed that its product had been fingered not because it was the most hazardous but because the company had produced more toxicological information than its competitors. Shell observed:

...the double standard in the Recommended Decision could well be interpreted in an ominous way by industry. The heptachlor mouse experiment is nine years old. From all the evidence on the record in this case, nothing has been done since then to conduct confirmatory tests.... Shell, on the other hand, as we have said, has spent over \$10 million looking at the mouse, rat, dog, monkey and its industrial workers. Are the American people to understand that the lesser the research, the greater the chance that EPA will give [its] competitors a regulatory assist by banning the competitive product?¹⁸⁹

A similar argument can be made, with perhaps more force, for the case of toxaphene. This chlorinated hydrocarbon is by some margin the best seller among insecticides (its volume of domestic use is 7 to 10 times higher than A/D), and its cumulative historical use in the U.S. is quickly approaching that of DDT at well over one billion pounds.¹⁹⁰ Studies conducted in the 1950's indicated that toxaphene

causes the same effects in the mouse liver that were observed for other chlorinated hydrocarbons. However, confirmatory carcinogenesis studies seem not to have been conducted for several years. The 1969 Mrak Commission urged "close surveillance" for the inexpensive insecticide, accurately presuming it would be a favored substitute for DDT,¹⁹¹ but lacking data on carcinogenicity, it did not list toxaphene as a chemical requiring additional study. EPA completed an internal review of the insecticide in 1973, but no regulatory action ensued. Following receipt of results from NCI mouse and rat studies in April 1977, EPA took initial steps toward cancellation in May.¹⁹²

Toxaphene has enjoyed relative obscurity until now because little is understood about its environmental fate. Produced by the chlorination of a mixture of camphenes, toxaphene has recently been found to comprise 175 different chemical entities, making detection in the environment and in tissue samples next to impossible. It is known to bioaccumulate, however. Another imposing complication is that toxaphene's major use is on cotton, and it is manifest that any regulatory initiative would (and now will) activate some of the same Southern passions that fanned the DDT controversy.

Two deficiencies are apparent in the selection of A/D and, more generally, in the general approach to cancellation. First, early selection was essentially made by EDF, and one can ask whether a public organization should relinquish the establishment of its priorities to any outside group, particularly when the group has only limited analytic resources. Second, there is value in providing an explicit, if by necessity imprecise, Agency ranking of cancellation candidates. Such an exercise in the case of A/D could not have established beyond any question that A/D was the proper choice, but it would have raised policy issues (e.g., whether body burden is an appropriate risk index) and identified research gaps (e.g., the environmental fate and carcinogenicity of toxaphene) that have largely escaped coherent analysis for the ensuing six years.

2. The Effects of Chemical-by-Chemical Cancellation

Reconsideration of the designation of A/D as the second domino leads to a larger question: Is the falling-domino approach appropriate for the regulation of pesticides? The answer is not a simple one, for the case-by-case approach has some subtle virtues. The DDT decision was of great value for Agency morale and signaled to the external world that a new order was in place; the A/D decision affirmed that DDT had not been an isolated political aberration. More significant, it launched intelligent deliberation on the establishment of objective criteria for regulating

environmental carcinogens (and quite possibly thereby created a framework for addressing risks of mutagenicity, teratogenicity, and other chronic health effects as well). In fact, the most enduring effect of the A/D proceedings may well be their contribution to the carcinogenicity sections of the new regulations for registering pesticides.

However, drawbacks of case-by-case actions are evident, and extend well beyond the problem of heavy administrative costs that is detailed in section C.

The need to develop objective standards for curtailing hazardous uses of pesticides, rather than by hoping they will evolve from a series of cancellation cases, has long been apparent. In fact, the 1972 FEPCA specifies reregistration of all pesticide products under new regulations four years after enactment.¹⁹³ One could argue that EPA's handful of large cancellation/suspension actions actually detracted from attainment of this deadline. The DDT, A/D, and H/C actions were highly visible, but a skeptic can claim that they only provided a coup de grace for compounds that were already economically moribund. These cases provided an impression of environmental progress that may have diverted attention from the formidable difficulties of implementing a systematic approach; a possible result is that environmental, legislative, and Agency leaders were late to comprehend that the pivotal reregistration program was falling very far short of Congressional intent.¹⁹⁴ (The Agency now suggests it may need 15-20 years to complete reregistration.)

Whatever the merits of the case-by-case approach in organizing and interpreting existing empirical information on pesticides, it has utterly failed to assure the generation of new information on the risks and benefits of pesticide use. In pesticide regulation, where uncertainty reigns, this is a crucial defect. As illustrated in the H/C and toxaphene examples, registrants have had incentive only to stand by, conduct little or no research on possible hazards, and hope that their product is not the next one chosen for cancellation. Known and suspected problems with these and many other compounds have been largely ignored since EPA was created. Only with the firm establishment of workable standards can the burden of showing safety be transferred to the firms that profit from pesticide use.

B. Scientific and Technical Information

1. The Delivery of Existing Information to Decision Makers

In principle, decision-making procedures should assure that all available scientific and technical information is promptly and accurately transmitted to the decision maker.

How does the A/D case measure up to this rule? Review of the two major issues, cancer and corn, provides a partial assessment of this question. A complete assessment, of course, is impossible, because relevant information that was unknown to decision makers is likely to be unknown to us as well.

a. Cancer. For the issue of cancer, the main question is whether all relevant animal test data were provided to policy makers. The fact that many of the studies were unpublished (or delayed in publication) may have had marginal effects on the A/D case. An early FDA mouse study suggesting tumorigenesis was only obscurely mentioned in the later 1962 article;¹⁹⁵ the FDA rat study, reporting higher overall tumor incidence, was unpublished for a decade;¹⁹⁶ Shell's 1965 mouse experiment was only informally reported until its publication in 1973, although the company had concluded that the findings were positive for carcinogenicity in March 1972; the existence of a positive 1965 NCI transplantation study became known by chance when an EPA attorney reviewed aging FDA files;¹⁹⁷ and an NCI rat and mouse experiment, already completed in 1974,¹⁹⁸ has still not been reported. Except for the imminent NCI study, however, the fact that these key studies were not in the public record did not seriously impede decision making once active preparation for hearing began. It did seem to impede earlier reviews, including those of the Mark Commission and the O'Brien Committee, that were essentially literature surveys. One can only speculate whether full and timely publication of these animal studies might have expedited the initiation of regulatory actions; the argument for this thesis is not overwhelming, given the slow pace of regulatory action on the much better understood DDT and a score of other "suspect" carcinogens.

The problem of identifying these studies was, in the long run, much smaller than that of comprehending their implications. No significant incidence of malignant tumors had been reported by researchers at the time of the A/D cancellation notice. The EPA trial staff found it necessary to perform fresh pathological and statistical analysis of both published and unpublished data. This re-analysis supported its claims of carcinogenicity in the mouse liver (for two strains), the mouse lung and the rat. Later questioning EPA's interpretation of the rat data, Shell arranged to have a panel of five pathologists re-examine some of the tissue slides on which EPA witness Reuber had discerned malignant tumors. They disagreed with Reuber's terminology.¹⁹⁹ EPA then had yet another pathologist analyze the same 20-year old slides; he saw hyperplastic nodulation that, he said, would inevitably progress to cancer. This untidy episode shows a range of interpretation among qualified histopathologists that must have confounded lay decision makers. The incident may indicate a need for a

mechanism to provide pathology review by non-partisan experts in cases like A/D. Reliance solely on an author's own interpretations, or on the sort of perfunctory peer review of an author's written findings that may attend the publication of scientific papers, has clearly proved insufficient for the needs of regulatory decision making.

b. Corn. Resolution of the corn issue involved imposing problems in information transfer, but just what EPA could have done to improve matters is far from clear. A starting point for analysis is an account of why farmers use aldrin and what substitutes are available. Shell submitted confidential salemen's estimates of aldrin's end uses, but as we have seen, there is reasonable doubt about which pests farmers believe they are controlling with aldrin, and the Agency was not originally apprised that only two insects of economic importance were controlled by A/D. Information on effective aldrin substitutes was also hard to find. The trial staff found EPA's sprawling registration files useless for this purpose and eventually compiled its list of substitutes from state officials' recommended alternatives. Shell demanded that EPA produce data from its registration files on the efficacy and toxicology of substitutes, presumably to support its argument that substitutes were no safer than A/D. Judge Perlman ordered OGC to comply in November 1973, but the trial staff never did.²⁰⁰ To the public, it may be difficult to believe that such information is not already known to Shell and its competitors, whether or not it is generally publicized; surely large modern chemical corporations have done studies of the efficacy of available compounds on various pests. Shell, however, insists it had no such data on aldrin, and Shell's rivals did not clamor to testify about the strengths of their products or the weakness of aldrin. It is possible that commercial factors blocked the transmission of existing information to EPA. It is also possible that use and efficacy data are not developed by pesticide suppliers. Ten million pounds of A/D would fill a very large box, but its sales represented only about 5 percent of the sales of Shell's Agricultural Chemicals Division,²⁰¹ and this minor product may not, in fact, attract extensive corporate research.

Similarly, the question of the extent of cutworm damage that would follow a ban on chlorinated hydrocarbon insecticides received no surfeit of objective information. Farmers lack the ability, and pesticide suppliers the interest, to assess this question systematically. It is an issue for entomologists. As in the case of mouse liver pathology, these experts' interpretations varied, with Shell witnesses seeing significant yield losses and EPA witnesses testifying that alternative cutworm control methods would reduce risk to nil. Shell saw irregularities in the way EPA handled information on this part of its case. Suspecting

that an EPA economist had withheld the pessimistic assessments of entomologists he had consulted, Shell asked for, and was denied, access to his trip report.²⁰² On the other hand, the trial staff sometimes doubted the objectivity of academic entomologists' estimates, feeling that widespread industry support of university research had inculcated a pro-pesticide orientation in senior members of the profession.

c. Conclusion. Despite these isolated difficulties, however, the A/D case is, on balance, exemplary in the identification and collection of existing written and unwritten knowledge. Although Shell is not much impressed with EPA decision making on A/D, a former company scientist has said, "There is no more complete scientific library on aldrin and dieldrin in the world than the transcript and record in the aldrin/dieldrin case."²⁰³ Equally important, perhaps, the decision-making procedures were highly successful in obtaining expert judgments from highly qualified specialists on both sides of the issue. On the question of human toxicology Shell presented experts with national reputations. Similarly, the EPA witnesses included appropriate scientists from NCI (notably Umberto Saffiotti, Associate Director for Carcinogenesis of the Division of Cancer Cause and Prevention, whose testimony was cleared by NCI)²⁰⁴ and senior statisticians from FDA and the American Cancer Society.

The Agency's success in gathering scientific information on A/D is, in part, a function of the adversary procedures employed. In comparison, the contribution of staff reviews and scientific advisory committees was uninspired. As far as is known, neither USDA nor the EPA pesticide program produced useful A/D policy reviews, and the O'Brien Committee left non-negligible gaps in its treatment of the cancer and corn questions. The Committee's relative strength, like that of the series of review committees that had reported on A/D in the 1960's, was in laying out an agenda for further research.

2. The Generation of New Information

Studies like the O'Brien Committee effort that recommend additional studies are, with justification, shrugged off as academic exercises that provide middle-term answers to short-term problems. What shruggers may overlook is that routinely ignoring the middle-term problems deprives future decision makers of adequate data. In fact, had the PSAC, Popper, Mrak, and even the O'Brien study recommendations been pursued more diligently, the A/D matter might well have been better (and more quickly) attended.

While existing information was managed well in the A/D case, the generation of new information on the key policy issues was all but neglected. The only known empirical studies set in motion to assist decision making were two animal feeding studies to investigate the mutagenicity and teratogenicity of A/D. Other important needs are apparent. Rat feeding studies performed to current standards might have clarified the issue of carcinogenesis. A critical analysis of the cutworm problem and an evaluation of alternative controls would have been welcome. Better information was needed on the actual routes of human exposure to dieldrin in the environment. No such studies were undertaken. The pesticide office found it impossible to support animal feeding studies suggested by the trial staff. EPA's Office of Research and Development (ORD) had minimal involvement (as fact finder or advisor) in the A/D case. "What we knew about aldrin and dieldrin," states a former ORD official, "is what we read in the newspaper."²⁰⁵

Two factors militated against original policy-related research in the A/D case. The first was a firm conviction that no study would produce results in time for the decision. But like mirages, even "imminent" decisions have a way of receding in ways the senses do not anticipate, and the actual time available is adequate for producing research results. To illustrate, NCI mouse and rat A/D feeding studies began more than a month after the O'Brien Committee released its report, and must have seemed pointless to harried EPA decision makers; but treatment ended at about the time the Mississippi chicken problem surfaced, four months before suspension.

The second inhibiting factor derives from the nature of research; it is inquiry into the unknown, and it is therefore quite possible that new findings will damage the sponsor's case. This deterrent works on both sides of the issue, of course. EPA's trial staff had no more appetite to support a field investigation and learn that the cutworm is virtually uncontrollable without aldrin than Shell did to fund a careful rat study that indicated carcinogenesis. The incentive for any party with interest in the dispute is to conduct either defensive research or none.

Considering its incentives, in fact, Shell's research program after A/D was initially questioned in the middle 1960's was appreciable. The effort may not quite be worthy of the company's lavish description--"the most exquisite and uniquely thorough investigation in the history of pesticides,"²⁰⁶--but it did elucidate important policy questions. One wonders if it was an anomaly, and whether in retrospect the firm now questions its decision to conduct its extensive series of mouse liver studies for different doses, treatment periods, and mouse strains. Certainly other registrants have proven much less cooperative. FEPCA

places a continuing burden of proof on registrants to attest to the safety of their products, and it is crucial that this burden not be allowed to choke private research altogether.

C. The Pros and Cons of the Adversarial Approach:
An Epitaph for Adjudication with all the Trimmings

The A/D hearings represented the formal adversary process in relatively pure form. It is a form, perhaps, that only an attorney can love--and, as even attorneys in EPA have recently concluded, a luxury the Agency can no longer afford. The current heptachlor/chlordane cancellation hearings are said to be its last use, and streamlined procedures are expected to replace it.²⁰⁷

1. The Problem of Delay

An advantage of methods used in the A/D case is the capability to assemble a large amount of existing information. The cost of this capacity should not be overlooked. One may question whether EPA decision making really required the world's largest scientific library on A/D, whether all 940 exhibits were necessary, whether a fraction of the 249 witnesses would not have sufficed (in particular, whether the testimony of 120 individual farmers could not have been adequately summarized in a careful survey report). As Spector observes, both sides have every incentive in a trial-type hearing to cram the record with all available evidence.²⁰⁸ In the A/D case, all parties charged their opponents with dilatory tactics. However, all agree that costs were high; Shell indicates it spent "several million dollars" on the case,²⁰⁹ EDF calculates its expenditure at \$300,000 (20 percent of its annual budget),²¹⁰ and EPA costs are estimated at \$5.5 to \$6.0 million.²¹¹ Shell espied another type of cost in the feeling of "physical and mental exhaustion" that was expressed by Judge Perlman. "Small wonder," the company complained, "that he had trouble understanding Shell's sophisticated evidence on the relevance of the mouse."²¹²

Tedious as the formal EPA hearing itself may have been, however, it only accounts for about one-fourth of the overall life of the A/D decision. A review of the problems of delay must address the larger context.

A/D was with EPA for 4 1/2 years, (had the wheels of impeachment turned as slowly, Richard Nixon would have completed his second term) and could easily have endured longer. Environmentalists observe that this is a long time to take to banish a carcinogen; but they should perhaps be thankful that (unlike Velsicol Corporation, which manufactures heptachlor and chlordane) Shell decided not to

exercise its right to resume the cancellation hearings after the EPA suspension decision was sustained.

Components of the overall duration of the A/D decision are shown in the accompanying table. It offers little comfort for those who would expedite major pesticide actions by administrative measures. Over 60 percent of the elapsed time was beyond the Agency's power to shorten. The two court appeals consumed one-third of the total period. Any zeal to reduce "relatively discretionary" delays (constituting 39 percent of the elapsed time) must be tempered by the realization that settlement negotiations require time, and if successful, they obviate the need for a lengthy hearing. In addition, depriving the trial staff of preparation time will almost necessarily put it at a greater disadvantage vis à vis better financed private sector intervenors. The current plan²¹³ to specify time limits for the hearings themselves seems reasonable, but will not have dramatic effects on the overall pace of decision making.

Whatever other procedural shortcuts are attempted, Judge Perlman would doubtless advise against the elimination of face-to-face cross-examination. The Judge has indicated that cross-examination was helpful in evaluating scientific evidence,²¹⁴ and that observation of witnesses' demeanor was also useful to him in parsing the case.²¹⁵

2. Adjudication and Comprehensive Policy Analyses

The A/D case was extensive; this does not imply that it was comprehensive.

It is instructive to consider A/D policy making in reference to the standard represented in Recommendation A of the Committee on Environmental Decision Making.²¹⁶ That recommendation calls for explicit and systematic identification of all the risks and benefits associated with each of several policy alternatives.

Several decision-making deficiencies are apparent in procedures employed in the A/D case. Because no one intervened to contest their cancellation, a large number of minor A/D uses received little serious attention; this represents an entire class of risks (e.g., poorer yields for cranberries) that escaped analysis even though the statute specifies that risks and benefits should be weighed for these registrations. The Appeals Court had sanctioned the neglect of minor crops in its DDT decision.

Another omission is on the risk end of the scale. The trial staff felt it had evidence from primate studies that A/D may cause neurotoxic and behavioral effects (e.g. inhibition of learning) in human beings at rather low doses.

DELAY IN ADJUDICATION -- THE ALDRIN/DIELDRIN CASE

A. CHRONOLOGY			B. THE SOURCES OF DELAY	
Interval	Date	Event	1) Relatively Non-Discretionary	
--	12/70	Env'tl Defense Fund Petition	Court Appeals	19 mos. (35%)
4 mos.	3/71	A/D Cancellation Notice (EDF Appeal)	1971 - 13 mos.	
13 mos.	5/72	Appellate Court Remand	1975 - 6 mos.	
1 mo.	6/72	EPA FR Notice	EPA's Formal Proceedings	14 mos. (26%)
14 mos.	7/73	Formal Hearings Begin	Cancellation - 13 mos.	
13 mos.	8/74	EPA Suspension Notice	Suspension - 1 mo.	
1 mo.	9/74	Suspension Hearing	2) Relatively Discretionary	21 mos. (39%)
1 mo.	10/74	EPA Suspension	Trial Preparation/	
6 mos.	4/75	Appellate Court Affirms	Settlement Negot. - 14 mos.	
1 mo.	5/75	EPA Cancels	Response to EDF Pet. - 4 mos.	
			Decision Making - 1 mo.	
			Oddments - 2 mos.	
TOTAL				54 mos. (100%)

However, this public health area is still largely uncharted territory, and trial staff emphasis on this line of argument was, reluctantly, reduced at the suggestion of the Judge.²¹⁷

A third defect is that it proved impossible to develop even gross quantitative information on human risk. The fundamental difficulty was that calculations of human cancer incidence are dependent on assumptions that, no matter how explicitly stated, attract rhetorical fury in an adversary setting. In April 1974 the trial staff submitted an analysis based on an accepted statistical technique that showed that, extrapolating from one of the Shell mouse studies, the chance of an American contracting cancer in his lifetime if A/D use continued was 0.001. This translates into 230,000 cases of cancer in the U.S.²¹⁸ Shell reacted vociferously, calling the suggestion "legal terrorism" and ridiculing the thought that A/D hazards could amount to 40 percent of the annual U.S. cancer incidence.²¹⁹ Judge Perlman observed that so many unverified assumptions were used that the estimate had little significance to him. The estimate does not appear in later OGC briefs. It does appear prominently, however, in the lead paragraph of the critical Washington Post article that appeared just before Train's suspension notice.²²⁰

3. The Problem of Polarization

The adversary process involves the argument of extreme positions in the expectation that the truth will become apparent to those responsible for making decisions. Whether or not truth emerges, polarization of attitudes and positions seems an ineluctable by-product of the process. Polarization in the A/D case had two facets, one probably overestimated by contemporary observers and the other, while more significant, less fully appreciated.

The first is commonly perceived as something of a holy war between scientists and lawyers engendered by the adversary nature of the A/D deliberations. The opposing camps, however, were not the formal parties, whose confrontations were largely confined to the hearing rooms: they were OGC lawyers and OPP scientists. To some participants, the acrimonious struggle was between inherently incompatible professions. Protesting scientists see the A/D case as the initial power grab by the lawyers, and OGC's Kolojeski recently reminisced, "I think EPA scientists gave me almost more trouble than Shell."²²¹ The single episode that seems most to roil both sides involves EPA pathologist Kent Davis, co-author of the two FDA mouse studies on A/D. Davis recalled that he had an early meeting with OGC attorneys at which he indicated that available data did not support the position the trial staff was advancing. He said that the lawyers then consulted a second scientist,

and, when he supported Davis, OGC began to seek experts outside EPA.²²² Both EPA scientists subsequently offered to testify for Shell. The trial staff contends that no EPA scientist, including Davis, even remotely met its criteria for scientific competence in its witnesses. The chasm deepened, and has not disappeared today.

The contretemps has occasioned imaginative explanatory theories. Some have worried that legal processes and scientific integrity are fundamentally incompatible, and one thoughtful writer speculates that the lawyer's need for winning inevitably conflicts with the scientist's need for truth.²²³

The theory seems unnecessarily elaborate. Davis' own recent expression of disdain of EPA's action on the insecticide Kepone disparages "the fantasies of clairvoyant histologists,"²²⁴ not of lawyers. Highly qualified research scientists were more than willing to serve as consultants and witnesses for EPA and EDF (and EDF is primarily a scientists' organization).

Nor can the conflict be easily ascribed to bureaucratic tension between OPP and OGC. Scientific staff within OPP itself has factional scars that are healing slowly.

The basic clash, it would seem, is a simple conflict in values between those who personally value the notable achievements of chemical technologies and those who value high standards of health and safety. Many of the protesting scientists in OPP had come to EPA from the pesticide programs in USDA and FDA. The missions of both organizations made them traditionally close to the producing sector. The OGC lawyers were, typically, committed young men drawn to the new Agency's mandate to protect the environment. The schism may have been a signal that the nation's shift in values, symbolized by the demonstrations of Earth Day 1970, had finally penetrated the regulation of pesticides.

The second variety of polarization is the absence, inherent in trial-type proceedings, of middle ground for policy. The trial staff argued for cancellation of most A/D registrations. Shell and USDA argued for their retention. The Judge was given almost no information or analysis on anything but these polar alternatives, and was left to his own imagination as to whether control measures short of cancellation were feasible say for controlling cutworms. He did not even know, for example, the proposed settlement terms--label restrictions and a cut-off date for A/D sale--of the prehearing negotiations. The only intermediate measures he could consider with confidence, it would appear, were the cancellation of some A/D uses and not others. The limitation is not restricted to the Law Judge; no one

involved in the hearing had any incentive to explore possible compromises.

As a result, EPA has banned four major pesticides in five years and may well have unthinkingly bypassed opportunities to develop new policy ideas. Questions that inhibited consideration of a cutworm compromise remain unanswered today. Do farmers read product labels, and will they comply with label restrictions even when it dictates use of more expensive pest control methods? Is it feasible to monitor illegal uses and enforce sanctions against violators? Could a "prescription-only" system for A/D use on cutworms in those states that set up appropriate programs have been implemented? Can pesticide salesmen be enlisted to help assure that aldrin was used only on fields easily recognized as cutworm targets? Could temporary registration of aldrin be granted when a region's cutworm population reached specified levels? Approaches like these can only be explored through cooperation between EPA, entomologists, pesticide suppliers, and pesticide users; a public hearing precludes such possibilities. In reserving judgment on the cancellation of some minor DDT uses in 1972, Administrator Ruckelshaus stated his often-quoted belief that "environmental problems should be parsed with a scalpel, not a hacksaw."²²⁵ Adversary hearings have not put any scalpels in the Administrator's kit.

NOTES

- 1 Preparation of this case study benefitted substantially from the thoughtful patience of two principal participants, John Kolojeski, formerly of the EPA Office of General Counsel, and Dr. M.J. Sloan, Manager for Regulatory Affairs of the Shell Chemical Company. Their gracious willingness to submit to interviews and to review drafts was indispensable. The incisive editorial assistance of Barbara Davies made the case study somewhat less incomprehensible.
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- 3 Public Law 92-516.
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- 5 7 USC Sec. 135(z) (2) (g).
- 6 Internal EPA Memorandum, April 1971.
- 7 EDF v. Ruckelshaus, 439 F.2d 584.
- 8 Ibid., p. 594.
- 9 FEPCA sec. 6(c) (1).
- 10 FEPCA sec. 2(1).
- 11 FEPCA sec. 2(bb).
- 12 Quoted in Robert Gillette, "DDT: In Field and Courtroom a Persistent Pesticide Lives On," Science, Vol. 174, (December 1971), p. 1109.
- 13 M.J. Sloan, "A U.S. Historical Account - Aldrin/Dieldrin Registrations, Uses, and Sales" (undated), p. 3.
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- 27 Ibid.
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- 31 H.B. Petty, "Aldrin-Dieldrin Statement," June 22, 1973, p. 2.
- 32 NAS, Pest Control, supra note 25, p. 29.
- 33 Delvo, supra note 29, p. 4.
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- 37 Herbert L. Perlman, "Recommended Decision on the Suspension of Heptachlor and Chlordane," Federal Register, Vol. 41, p. 7569 (December 12, 1975).
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- 54 Mrak Commission Report, supra note 49, p. 129.
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EXPLICIT CRITERIA AND PRINCIPLES FOR IDENTIFYING CARCINOGENS:
A FOCUS OF CONTROVERSY AT THE ENVIRONMENTAL PROTECTION AGENCY

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I. DESCRIPTION OF THE DECISIONS²

In an earlier version of this case study, three major initiatives in developing cancer policy at EPA from 1973 to 1976 were investigated, and a number of scientific and political issues associated with them were discussed. The three initiatives were (1) the use of "cancer principles" during the DDT, aldrin/dieldrin (A/D), heptachlor/chlordane (H/C), and Mirex proceedings and in rulemaking; (2) the efforts to establish a consistent "national cancer policy" among federal health research and regulatory agencies, and efforts coordinated by the Office of Research and Development (ORD) to generate a comprehensive list of options for use by the Administrator of EPA in regulating carcinogens; and (3) the establishment of agency-wide procedures for assessing the risk to human health from carcinogens and, in particular, new procedures for evaluating the risks associated with the use of pesticides and the economic implications of regulating them.

The use of "cancer principles" has been widely misunderstood and severely criticized by segments of the scientific community. The use of principles, their origins, and opposition to them are discussed in this volume. A limited number of copies of updated versions of the discussions of the other initiatives are available upon request.

II. INTRODUCTION³

The cancer principles used by EPA refer to a number of different, although related, things. First, the principles are sets of summary statements distilled from the enormous records of hearings held on individual pesticides. There were 7 principles from the DDT case, 9 from the A/D case, 9 and two sets of 17 from the H/C case, and yet another set of 17 from the Mirex case. Second, the principles refer to the application and expansion of the summary points in the actual decisions (policies) of the Administrative Law Judges and the Administrators in the various pesticide cases. Some of the confusion generated over the principles was due to the various forms of EPA's cancer principles and to the various discussions in formal decisions that incorporated the summary statements.

Third, no matter what form the EPA principles take, they ultimately refer to the criteria and principles that were

developed by expert scientific committees over the past 25 years and that set a framework for the evaluation of carcinogenicity. Much confusion arose with respect to the underlying basis for EPA's cancer principles; many scientists were either unfamiliar or in basic disagreement with the surprising consensus of views--although not unanimous--among the many national and international committees that grappled with the problem of identifying carcinogens and evaluating the risk to human beings.

The criteria and principles discussed by expert committees are not scientific laws or demonstrable facts, but tenets that include many presumptions. The data on the induction and progression of cancer can be interpreted many ways, and much of the difference in interpretations rests on differing value judgments. Indeed, one principal reason that expert committees turned their attention to the development of explicit criteria and principles was to treat the uncertainties in carcinogenicity testing. They sought to formulate reasonable presumptions to guide carcinogenicity testing and evaluation in the absence of better knowledge, and significant advances in understanding cancer could alter, and would certainly clarify, a number of the principles.

To place the principles in proper context, it is first necessary to explore briefly what is known about the causes of cancer and then review the early development of and statutory framework for the cancer principles. The use of cancer principles in adjudicatory hearings and in rulemaking are then discussed, and the controversy over their use is traced. Organized opposition and an attempt at peer review are discussed to further clarify the controversy.

A. The Nature of the Disease

Cancer is a group of dreaded and costly diseases that are characterized by rapid and unrestrained growth of populations of abnormal cells.⁴ The body's natural defenses do not appear to be fully capable of reversing the disease,⁵ and its development is generally irreversible and autonomous. The early cellular events and the causative factors leading to initiation and progression of the disease are not yet fully understood, although intensive research over the last decades has greatly increased knowledge of cancer.

Once the initial carcinogenic events are triggered, the resulting aberrant cells are capable of progressing to stages in which normal tissue is invaded and cancer cells spread throughout the body and continue their course, even though the agent responsible for inducing the disease may no longer be present. There also is evidence--though not

definitive--that certain forms of cancer originate from a single transformed cell.⁶ The effects of either continuous or occasional exposure appear to be additive and in some cases synergistic.⁷

Typical latency periods for cancer are 15-40 years,⁸ which means that one must wait that long before detection is possible. Even if early detection were routinely possible, treatment of cancer is not sufficiently successful to permit any confidence that once recognized the disease will be cured. Because of the latency of cancer, there are multiple opportunities for exposure to a wide range of carcinogenic substances, and it is extremely difficult, and often impossible, to identify the causative agents. From studies in animals, it is found that carcinogenic chemicals act in a number of different ways and are classified according to their mode of action as direct acting carcinogens, procarcinogens, and co-carcinogens.⁹ However, from a regulatory standpoint, it is not useful to distinguish between these modes of action.

B. Cost and Extent of Cancer

Approximately 358,400 people died of cancer in 1974 in the United States, and about 1 million people are being treated for the disease.¹⁰ The General Accounting Office estimates¹¹ that the annual cost of cancer is as high as \$15 billion, of which \$3-5 billion represents the costs of direct care and treatment with the remainder attributed to loss of earning power and productivity.

Cancer is now the second leading cause of death in the United States behind heart diseases. In 1900, cancer was ranked eighth and infectious diseases were ranked first. Some of the increase in the cancer mortality rate since 1900 may be attributed to the average increased age of the population as a result of progress early in the century against infectious diseases. In essence, people with cancer who might have died from other diseases now live long enough to develop cancer. Improved reporting methods may account for a portion of the increase in the cancer mortality rate; that is, cancer deaths previously attributed to other diseases are now properly attributed to cancer. However, even after these factors are taken into account, the increase in the cancer mortality exceeds predictions.¹² The size as well as the age of the population may also account for a part of the increase in the sense that a more genetically diverse and older population of today may consist of more people who are susceptible to cancer.

C. Environmental Origins of Cancer

While the overall cancer mortality rate is increasing despite advances in treatment, the rate differs markedly for specific sites in the body, which in turn differ by sex.¹³ These rates are adjusted for differences in the ages of the compared populations. For both males and females, mortality rates from stomach cancer have declined steadily in the United States. For males, and more recently for females, mortality rates from lung cancer have dramatically increased (for males the rate has increased 20-fold in the last 40 years). Mortality rates for cancer at specific sites also differ according to race, geographical region, and a wide range of other demographic variables. Interpretation of cancer mortality rates is obviously complex and even the decrease in stomach cancer rates is not understood.

One thing has emerged, however, from comparisons of cancer mortality rates among different countries, even though precise calculations are not possible. As much as 60 to 90 percent of cancer is related to environmental as opposed to hereditary factors.¹⁴ Examples of such environmental factors include smoking habits¹⁵ (particularly cigarette smoking); alcohol consumption;¹⁶ dietary habits;¹⁷ exposure to various forms of radiation,¹⁸ such as x-rays, radioactive materials, and ultraviolet radiation from the sun (although skin cancer is a prevalent form of the disease, it is one of the least frequently fatal forms¹⁹); a wide range of industrial chemicals and minerals,²⁰ such as bis(chloromethyl)ether, vinyl chloride, beta-naphthylamine, benzidine, arsenicals, nickel carbonyl, various soots and tars, and asbestos; and certain naturally occurring compounds, such as aflatoxins, which are secreted by certain molds.²¹ Although there is considerable evidence that chemical and physical agents cause cancer, viruses may yet prove to be a direct or perhaps secondary factor in carcinogenesis.²² As noted, many of these factors interact in ways that still elude scientists and physicians, and environmental factors, as well as factors associated with the genetically affected defenses of each individual, determine whether cancer will develop.²³

D. Strategy for Control: New Emphasis on Prevention

The incidence of cancer appears to be rising. Because it is such a dreaded and costly disease for which treatment has not been fully successful, and because evidence has mounted that cancer is environmental in origin, public pressure has led decision makers to seek strategies for control other than the quest for a cure. Measures designed to reduce or eliminate exposure to carcinogenic substances have been of concern for many years. Expert committees, formed since the early 1950s to advise national and

international public health agencies, have developed principles to guide the identification of carcinogens for the purpose of preventing exposure to them. More recent public concern about cancer has led to increased emphasis on prevention as a means of controlling cancer, and the proper emphasis on prevention has been controversial.²⁴

The broad scientific and political issues surrounding efforts to control cancer by means of prevention are reflected to a large extent in the controversy over the use of explicit cancer principles at EPA. First, the evidence that establishes the carcinogenicity of most substances is, in strict scientific terms, highly uncertain at best. Often it requires extrapolations from poorly conducted animal studies in the absence of human data. Quantitative extrapolations to determine the level of risk are even more tenuous. The incidence of tumor formation and the dose from animal studies are translated into human risk in precise mathematical terms but with little direct knowledge of how to make such an extrapolation in biological terms.

Second, the priorities for taking regulatory actions to prevent exposures to carcinogens are often called into question. Certain substances of known carcinogenic activity are not regulated whereas others for which less evidence exists are regulated. An illustration is the situation with respect to tobacco smoke. Cigarette smoking has been estimated to account for 40 percent of all cancer in white males²⁵ and is an associated and synergistic risk factor with many other factors, as, for example, with alcohol consumption²⁶ and exposure to asbestos.²⁷ However, tobacco is not regulated as a carcinogen and is virtually exempt from such regulation; in fact, it is subsidized through agricultural price supports and, until recently, through exports in conjunction with foreign aid programs.

Clearly, the voluntary nature of exposure to tobacco smoke and the involuntary nature of exposure to other substances, such as industrial pollutants, pesticides, and food additives, affect whether such substances are regulated as carcinogens. For this reason, efforts to control cancer by means of prevention through removal or reduction of exposure to substances of lower risk than tobacco smoke are plagued by criticism of misplaced emphasis. However, even if cigarette smoking is not regulated, the impact on cancer incidence of reduced exposure to other potentially carcinogenic substances, some of which may interact with smoking, is still likely to be significant.

Third, because of the uncertainties involved, the inevitable clashes between regulatory agencies and the regulated segments of society are fueled, and considerable delays have occurred between initial identification of carcinogenic substances and final regulatory actions. Such

delays have often led to increased public pressure for action, which in turn has exacerbated the problems faced by regulatory agencies.

The cancer principles used by EPA were developed as part of the strategy to control cancer by preventive measures. The controversy over their use arose largely because their purpose and origins were widely misunderstood and because of confusion over the various forms in which they appeared.

III. CANCER PRINCIPLES

A. Identification of Carcinogenic Substances

If regulatory action is to be taken to control cancer by preventing exposure to potential carcinogens, presumptions about what constitutes carcinogenicity, despite all the uncertainties, are needed. The cancer principles used by EPA serve this purpose. They indicate the minimum kinds of data for identifying carcinogenic chemicals and provide a reasonable framework for interpreting the data, even if the conditions for the studies are not optimal. The reports of expert committees, from which the cancer principles are derived, discuss in addition to minimum requirements for inferring carcinogenicity the optimal conditions for carcinogenicity testing.

Two principal kinds of evidence establish the carcinogenicity of a substance: epidemiological studies of human experience and bioassays with test animals. In both cases, the occurrence of a statistically significant incidence of tumors, especially of a malignant nature, induced by an agent in an exposed group when compared to a control group characterize the carcinogenic potential of a substance.

In the case of human studies, the best data exist on workers who often are exposed to higher levels of substances than the general population. Indeed,

[e]xisting epidemiological methods are adequate for demonstrating carcinogenic hazards in the work environment even when the excess risk is rather small and the disease in question is relatively common in the general population.... [But]...this capacity for recognition depends on the actual occurrence of the disease and, by itself, has no preventive or control value.²⁸

Aside from the ethical problem of relying on studies in workers or other humans to identify carcinogens "...[t]hese methods are imperfect, however, and limitations in study

design and types of data should be borne in mind when occupational carcinogenesis is studied."²⁹

Thus, negative findings in epidemiological studies do not carry the same weight as positive evidence. A continual complicating factor in epidemiological studies is the long latency of cancer. As noted earlier, it provides numerous opportunities for exposure to many different agents, not just the one under study. Adequate controls are difficult to establish for this reason and because it is not possible to find unexposed individuals for substances widely dispersed in the environment.

Also, epidemiological study groups are often small and, thus, insensitive, so that responses to a carcinogen may not be seen due to the wide range of susceptibility to carcinogens among individuals.³⁰ Furthermore, even if definitive results were easier to obtain from epidemiological studies, the latency of cancer means a delay in establishing the carcinogenicity of a substance while additional people are exposed. Epidemiology is a strong tool for identifying carcinogens to which people have already been exposed and as a check on substances not detected by animal studies. However, because definitive results are so difficult to obtain, positive findings in animal studies generally outweigh negative findings from epidemiological studies.

Investigators have long relied upon laboratory studies under controlled conditions to study the carcinogenic potential of chemicals. However, present knowledge is not sufficiently advanced to allow a precise determination of whether a carcinogen identified solely by means of a bioassay in animals will or will not be carcinogenic in humans and if so, at what site and with what incidence. To study the effects on humans of substances identified as carcinogens through animal studies is not ethically nor practically feasible; however, it is reassuring that there is a good correlation between substances known to induce cancer in human and also studied in animals:

A major source of data on carcinogenicity comes from bioassays in experimental animals. Experience has indicated that, with one or two possible exceptions, compounds that are carcinogenic in humans are also carcinogenic in one or more experimental animal bioassay systems. In addition, several compounds first detected as carcinogens in experimental animals were later found to cause human cancer. Demonstration that a compound is carcinogenic in animals should, therefore, be considered evidence that it is likely to be carcinogenic in humans, unless there is strong evidence in humans to the contrary.³¹

While studies in laboratory mammals (most often mice, rats, and hamsters) are clearly necessary for carcinogenicity testing and solve many of the problems associated with reliance on epidemiological studies, they are not capable of assuring absolutely that a chemical will be safe. In 1961, a joint committee of the Food and Agricultural Organization and the World Health Organization (WHO) stated that:

...tests on experimental animals cannot provide irrefutable proof of the safety or carcinogenicity of a substance for the human species. However, it is at least reassuring that the known carcinogenic activities of certain chemicals in man are similar.³²

Studies in animals involve many variables that may be hard to control and pose problems for the purpose of identifying carcinogens. For example, various kinds of environmental stress can increase the incidence of tumors in mice;³³ also, early termination of a study or incomplete tissue examination may lead to a failure to detect a carcinogenic response. Rodents are the species of choice because of their long history as test animals for carcinogenicity, ease and low expense for care and feeding, and short lifetime of 2 years. However, mice, rats, and hamsters when tested with the same agent often do not respond to carcinogens in exactly the same way nor exactly to the same extent and thus differ when compared to one another or to humans.³⁴ There are apparent but poorly understood differences in the absorption, distribution, metabolism, and excretion of substances between rodent species and humans. However, even with such uncertainties, a reasonable degree of control of the most troublesome variables can be achieved.³⁵

As for epidemiological studies, negative findings from animal studies often do not carry the same weight as positive findings. In 1969, the International Union Against Cancer published a report on testing, which stated:

It is generally recognized that negative results of biological testing are less significant than positive results, in relation to human application. This is all the more true when testing procedures are inadequate.³⁶

B. Early Development of Principles

The scientific community started to develop guidelines for carcinogenicity testing and for evaluating the results in the mid 1950s. The expert committees of national and international organizations prepared reports³⁷ that were

broad in scope and outside the context of decisions regarding individual chemicals. In 1969, a scientific panel reported the following:

General principles and criteria for evaluation of carcinogenic hazards have been laid down by several expert committees convened in the last 15 years by scientific and public health agencies such as the World Health Organization, the Food and Agricultural Organization, the International Union Against Cancer, the National Academy of Sciences-National Research Council, the European Committee on Toxicity (Eurotox), and the Food and Drug Administration Committee on Protocols for Safety Evaluation [references omitted]. Recommendations made in these reports express a remarkably unanimous view on the general principles and criteria to be followed for carcinogenesis safety evaluations, widely accepted in principle by the scientific community [references omitted].³⁸

The reports referred to above and subsequent ones are not unanimous on all points, but they do indicate that the criteria and principles were widely accepted.

In 1970, a committee of the National Research Council stated that it was:

...not the purpose of this report to present another set of principles and procedures, but rather to review the purposes and value of what have become conventional procedures....³⁹

The committee discussed the difficulty in carrying out controlled epidemiological studies and stated that, although desirable, they have limited predictive value. The Committee concluded:

It is clear that appropriate and well-executed animal studies are more likely to provide a substantial background of biological data from which to judge safety than are studies in man alone.⁴⁰

In a discussion of the evaluation of the carcinogenic hazards, the Committee stated that:

[O]n both ethical and practical grounds, the possible carcinogenic effects of chemicals to which man might be exposed must be determined in experimental animals, generally in short-lived species. The extrapolation of the results of these determinations to man rests on two basic findings:

1. Despite a great variety of studies, no significant aspect of the natural occurrence, induction, and properties of cancer has been shown to differ fundamentally between man and experimental animals.

2. Considerable assurance of the general applicability of the tests can be derived from the fact that the chemicals generally known to be carcinogenic in man also induce neoplasia [tumors] in experimental animals.

Many clear differences in the activities of chemical carcinogens in various species exist, however, and the unpredictable nature of species differences is the principal limitation to the extrapolation of results from studies with experimental animals to man.*1

More recent reports do not differ on these points. EPA was required by the Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA)*2 to regulate pesticides, some of which when tested in animals showed evidence of carcinogenicity. Thus, EPA had to apply criteria and principles developed by the scientific community about which there was a consensus of opinion but not total agreement.

C. Statutory Framework

FIFRA requires the Administrator of EPA to register all pesticides; as a safeguard, the Act provides for the cancellation of a registration if "in accordance with widespread and commonly recognized practice" continued use causes "unreasonable adverse effects on the environment," which are further defined as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of any pesticide." The Administrator may hold a hearing to determine whether a registration should be canceled, or any adversely affected party may request one. If an "imminent hazard" exists during the time required for a hearing, the Administrator may suspend the registration; the registrant may then request an expedited hearing to determine if an imminent hazard exists. In the event of an emergency, the Administrator may immediately suspend a registration without holding a hearing.

To some extent in the DDT case, but to a great extent in the A/D, H/C, and Mirex cases, carcinogenicity was the principal effect that posed unreasonable risk to humans. FIFRA provides a 90 day period for a final decision in a cancellation proceeding. EPA procedures divide the time between the Administrative Law Judge (ALJ), 25 days for a

recommended decision, and the Administrator, 65 days for a final decision. The time permitted for a recommended decision in a suspension proceeding is only 8 days, with 9 days permitted for a final decision. For this reason, the arguments distilled from the enormous records by the numerous parties in the proceedings, particularly in suspension cases, are very important. EPA used cancer principles as points summarizing the criteria and principles developed by the scientific community. The reports containing the criteria and principles were entered into the hearing records of the cancellation and suspension proceedings.

The hearing records of major cancellation proceedings often exceed 20,000 pages. For suspension proceedings the records have typically been between 5,000 and 10,000 pages. The ALJ in one of the suspension proceedings said upon submission of his recommended decision to the Administrator:

...we have exhausted ourselves in issuing this decision within the impossible time constraints imposed by the statute and the rules of practice.*3

D. Use of Cancer Principles in the DDT Cancellation Proceeding

The first time cancer principles were used by EPA in a formal proceeding was in its final brief in the DDT cancellation proceeding.** The brief contained 7 "...general principles applicable to determination of carcinogenic hazards...." (listed in Table 1). The final decision of the Administrator*5 contained the finding that "DDT presents a carcinogenic risk,"*6 and several of the general principles were applied to specific data on DDT. The 1972 order of the Administrator cancelled all registrations of DDT except for public health or agricultural pest quarantine uses.

Although the principles were generated within the narrow context of pesticide proceedings, they have obvious implications for other programs at EPA. Once the criteria for defining a carcinogen were made explicit and entered into the record of the formal proceeding, the need would be diminished, in future proceedings of this type, for many of the same experts to submit the same documents or testify on the same subjects simply to establish the criteria for evaluating the data on carcinogenicity for the case in question. In future proceedings, the data in question could be evaluated on the basis of the criteria already established. The criteria could also be adopted for other programs.

TABLE 1
CANCER PRINCIPLES FROM EPA's FINAL BRIEF IN THE
DDT CANCELLATION HEARING, MARCH 2, 1972*

The general principles applicable to determination of carcinogenic hazards are as follows:

1. Any substance shown conclusively to produce tumors in animals should be deemed potentially carcinogenic in man, except when the effect is caused by physical induction or where the route of administration is grossly inappropriate in terms of human exposure.
2. Carcinogenic data on man is acceptable only when it presents critically evaluated results of adequately conducted epidemiological data.
3. No level of exposure to a chemical carcinogen should be considered toxicologically insignificant for man [reference omitted].
4. Carcinogenic bioassays should include two species of animals of both sexes, with adequate control animals subject to lifetime administration of suitable doses including highest tolerated doses by routes of administration including those by which man is exposed [reference omitted].
5. Negative results should be considered superseded by positive results, which should be deemed definitive unless new evidence conclusively proves that the positive results were not causally related to exposure [reference omitted].
6. An implication of potential carcinogenicity should be drawn both from tests which induce benign tumors and those resulting in tumors more obviously malignant [reference omitted].
7. The principle of zero tolerance is valid and should be expanded [reference omitted]. Although environmental exposure is causally related to human cancers [reference omitted], relatively few of the chemicals that have been adequately tested induce tumors [reference omitted]. In the Bionetics study [reference omitted] only 11 pesticidal chemicals showed significantly elevated tumor incidence, while 89 compounds showed no significant indication of tumorigenicity.**

* References to exhibits and documents entered in the record and to portions of the transcript of the hearing have been omitted for convenience.

**Controversy exists concerning the classification of tumors as benign or malignant. One segment feels that the benign tumor is nothing less than a stage in the development of malignancy, therefore, one should consider all tumors potentially malignant. [Reference omitted.] Another group would rely largely upon the observation of either invasiveness or metastasis as an indication of malignancy (i.e., carcinogenicity).

Because the question of carcinogenicity was not as great an issue in the DDT hearing as it was in subsequent proceedings on A/D, H/C, and Mirex, the use of cancer principles in the DDT case was not controversial. The controversy arose later in conjunction with their use in the A/D suspension proceeding. The controversy centered on the language of the principles and the uncertainties inherent in the carcinogenicity evaluations.

E. Use of Cancer Principles in the Aldrin/Dieldrin Suspension Proceeding⁴⁷

EPA's final brief in the A/D suspension proceeding⁴⁸ contained 9 principles (see Table 2) that:

...represent the most advanced research findings and policy of both national and international cancer experts and agencies.⁴⁹

These principles were offered as "established principles of carcinogenicity which can be applied to individual substances to determine their human cancer hazard."

The principles were based on material in the record consisting of various reports of expert committees and the statements of 13 medical experts who had testified during the A/D cancellation and suspension proceedings. Detailed documentation for the principles consisted of citations from the transcript and exhibits, and also included some discussion of contrary evidence filed by Shell Chemical Company, the sole manufacturer of A/D and the principal registrant in the hearing.

The 9 principles were largely derived from the testimony and exhibits submitted by Umberto Saffiotti,⁵⁰ formerly the Associate Director for Carcinogenesis of the Division of Cancer Cause and Prevention of the National Cancer Institute (NCI). Later, however, Saffiotti claimed that the principles were naive and failed to represent the real science to which he alluded in his testimony.⁵¹

In suspending A/D, both the recommended decision of the ALJ and the decision of the Administrator incorporated the substance of the 9 cancer principles but without explicit reference to them as principles; most of the incorporated principles were reworded and used to discuss the data on A/D. An example of this can be seen by tracing the first principle: "a carcinogen is any agent which increases tumor induction in man or animals," which in the Administrator's decision was stated as follows:

The once-significant distinction between tumors and cancers, or between tumorigenic and carcinogenic

TABLE 2

CANCER PRINCIPLES FROM EPA'S FINAL BRIEF IN THE

ALDRIN/DIELDRIN SUSPENSION PROCEEDING, SEPTEMBER 16, 1974

1. A carcinogen is any agent which increases tumor induction in man or animals.
2. Well-established criteria exist for distinguishing between benign and malignant tumors; however, even the induction of benign tumors is sufficient to characterize a chemical as a carcinogen.
3. The majority of human cancers are caused by avoidable exposure to carcinogens.
4. While chemicals can be carcinogenic agents, only a small percentage actually are.
5. Carcinogenesis is characterized by its irreversibility and long latency period following the initial exposure to the carcinogenic agent.
6. There is great variation in individual susceptibility to carcinogens.
7. The concept of a "threshold" exposure level for a carcinogenic agent has no practical significance because there is no valid method for establishing such a level.
8. A carcinogenic agent may be identified through analysis of tumor induction results with laboratory animals exposed to the agent, or on a post hoc basis by properly conducted epidemiological studies.
9. Any substance which produces tumors in animals must be considered a carcinogenic hazard to man if the results were achieved according to the established parameters of a valid carcinogenesis test.

Please note: These principles were followed by 27 pages of citations from reports and testimony to support each principle and to place them in context.

substances, has lost much of its validity with the increasing evidence that many tumors can develop into cancers. Thus, for purposes of carcinogenicity testing, they should be considered synonymous. [reference omitted]⁵²

Thus, the manner in which the 9 principles were used in the Administrator's A/D decision was limited. They did not, in their original form, directly provide the basis for evaluating the carcinogenicity data. However, they did represent the conceptual framework within which the carcinogenicity data were evaluated.

Attention was focused on the principles from A/D by a number of publications, such as Chemical and Engineering News (C&EN).⁵³ An article, "EPA broadens its definition of carcinogen," published on October 14, 1974, said of the A/D suspension decision that a "...new and apparently precedent-setting criterion for determining carcinogenicity of a substance was used...." The article cited the Administrator's opinion in which he said that for the purpose of carcinogenicity testing, tumorigenic and carcinogenic substances are synonymous. The article stated:

[t]his interpretation could have a far-reaching impact on EPA regulations of chemical substances. However, it is in sharp contrast to policies of other agencies, such as the Food and Drug Administration, which define carcinogenic substances as those that actually cause cancerous tumors.

In a letter to the editor of C&EN of October 23, 1974, the Administrator said that the article was incorrect. He wrote:

[t]he definition of a carcinogen which EPA applied to aldrin and dieldrin is exactly that presently used by the Food and Drug Administration in regard to the Delaney Clause, as they stated in the hearings of the Agriculture-Environmental, and Consumer Protection Appropriations Subcommittee for 1975, part 8, page 524: 'A substance is considered to be a proven carcinogen in regard to the Delaney Clause if it has been conclusively demonstrated to cause tumors (by induction of a tumor type not usually observed, the production of an increased incidence of a tumor type frequently seen, or by the appearance of such tumors at an earlier time than would be otherwise expected) in at least one mammalian species.'

A letter⁵⁴ from the Associate Commissioner for Science at the Food and Drug Administration (FDA) to the Chairman of

the Subcommittee on the Environment of the Senate Commerce Committee also illustrates the controversy. He stated:

Mention has been made earlier of the difficulty and ambiguity concerning the final assessment of carcinogen testing.... [I]t is of importance to note the broadening by EPA of its definition of a carcinogen in their recent brief in the aldrin/dieldrin suspension hearings [he then referenced the articles in C&EN and Pesticide Chemical News⁵⁵]..... Although the Agency stated [in its final brief] that 'the above principles represent the most advanced research findings and policy of both national and international cancer experts and agencies,' it should be emphatically emphasized [sic] that there is by no means universal acceptance of many of the above principles....

The District of Columbia Circuit Court of Appeals reviewed the suspension decision of the Administrator⁵⁶ and concluded that EPA's order to suspend registration of certain uses of aldrin and dieldrin:

...is a rational exercise of discretion, rather than arbitrary agency action.... The Administrator's conclusion is within the scientific expertise of the agency, and is not infected by error of law.

The court cited the Administrator's conclusion that A/D

...presented an 'imminent hazard' to man on the basis of data indicating that it is carcinogenic in five strains of mice and, as corroboration, indications that 'there is a strong probability that Aldrin/Dieldrin is a carcinogen in rats as well as mice.'

This last statement is predicated upon a prior ruling by the court:

We have cautioned that the term 'imminent hazard' is not limited to a concept of crisis. 'It is enough if there is a substantial likelihood that serious harm will be experienced....'

and on FIFRA:⁵⁷

The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole [reference omitted].

The court further explained that the term "substantial evidence" means:

...something less than the weight of evidence....
The possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence [reference omitted].

Upon resumption of the cancellation proceeding, Shell voluntarily withdrew its application for the registration of A/D and ceased manufacture.⁵⁸

In dismissing Shell's assertions that A/D are not carcinogenic, the court discussed many of the points in the 9 principles (the decision-making tool or framework for policy) as they were incorporated into the decisions of the Administrator and the ALJ (the policy).

An illustration of a decision in which the principles and policies established in the A/D decision led to confusion about what the principles and policies actually were involves an appeal for the use of DDT. The State of Louisiana appealed to the Administrator for an exemption⁵⁹ to use DDT on an emergency basis for cotton,⁶⁰ a use not permitted under the Administrator's 1972 cancellation order.⁶¹

The request was denied, and after discussing the evidence that there is a synergistic effect between DDT and dieldrin, the Administrator said:

The principles of chemical carcinogenesis which I have been guided by in my evaluation of this experimental evidence are set forth in my discussion of carcinogenicity in the Aldrin/Dieldrin Suspension Order....⁶²

Thus the principles referred to in the Louisiana DDT decision are not the summary points in EPA's brief but rather the expansion of them in the A/D suspension decision.

F. Use of Cancer Principles in the Heptachlor/Chlordane Cancellation and Suspension Proceedings

In the Agency's first pretrial brief in the cancellation of H/C, the 9 cancer principles used in the A/D suspension proceeding were presented. This is the first example of the Agency using the cancer principles at such an early stage to establish the criteria for evaluating the carcinogenicity of a pesticide. The principal registrant of H/C, the Velsicol Chemical Corporation, opposed this use of the principles.

At this pretrial stage, Velsicol focused on principle 2, concerning the characterization of benign as well as malignant tumors as a carcinogenic hazard, and principle 7, concerning threshold exposure levels.

Early in the H/C cancellation proceeding, Velsicol sought⁶³ to have the 9 cancer principles referred to a committee of the National Academy of Sciences (NAS) for review. Prior to 1972, a committee chosen by the Administrator from a list of experts nominated by the NAS would review relevant questions during cancellation proceedings at the request of any of the involved parties. After an amendment to FIFRA in 1972, review by an NAS committee was within the discretion of the ALJ, but industrial registrants understandably continued to maintain they were entitled to review by NAS scientists.

Velsicol's motion for referral cited Tepper's letter as evidence "that the principles and their factual basis require such review."⁶⁴ That is, Velsicol argued that agreement on the principles was not unanimous, nor were they universally accepted. Also adduced in support of the motion was a memorandum from the Toxicology Branch of the Registration Division in the EPA Office of Pesticides Programs (OPP), in which it is strongly suggested that benign tumors be considered a carcinogenic hazard only when they occur simultaneously with malignant ones.

EPA opposed the motion to refer the principles to NAS on the basis of the policy established in the DDT and A/D decisions and the rulings of the U.S. Courts of Appeals in both cases.⁶⁵ The EPA brief opposing the motion⁶⁶ cites publications by both United States and international agencies in support of the two disputed principles.

Velsicol's motion was denied by the ALJ, and EPA moved⁶⁷ to have certain facts officially noticed and incorporated into the record. The first 17 of the 38 facts were cancer principles (see Table 3). These principles consist of the exact language or slight rewordings of the language found in the various decisions in the DDT and A/D cases. They contain none of the exact language of the 9 principles from EPA's final brief from the A/D case, although the concepts embodied in all 9 are part of the 17.

Thus, as in the EPA brief opposing Velsicol's motion to refer the principles to NAS, the Agency sought to link the principles to established policy in published decisions and only indirectly to the reports of expert committees.

USDA then moved to refer to a committee of NAS scientists the question of whether the present uses of H/C constitute a carcinogenic hazard to man. USDA sought a determination of:

TABLE 3

CANCER PRINCIPLES FROM EPA'S MOTION TO TAKE OFFICIAL NOTICE
IN THE HEPTACHLOR/CHLORDANE CANCELLATION PROCEEDING, JUNE 27, 1975

1. Cancer is a major and increasing cause of death and morbidity in man. It imposes upon society an immense burden of death, suffering, and economic loss. (Recommended Decision, In re: Shell Chemical Co., FIFRA Docket No. 135, et al., 23 (hereinafter cited as ALJ), 39 F.R. 37252).
2. Cancer may be induced by many factors including exposure to chemicals. (Opinion of the Administrator, In re: Shell Chemical Co., FIFRA Docket No. 145, et al., (hereinafter cited as A/D), 39 F.R. 37267).
3. Chemical carcinogenesis is characterized by a long latency period which in humans may be as long as 20, 30 or 40 years between exposure and the appearance of symptoms of the disease. (EDF v. EPA, 510 F. 2d at 1299; A/D, 39 F.R. 37270; ALJ, 39 F.R. 37252).
4. Once a carcinogenic response has been triggered the development of cancer is irreversible. (EDF v. EPA, 510 F. 2d at 1298; ALJ, 39 F.R. 37252).
5. Given the long latency period of cancer and its irreversibility, in the case of a chemical for which there is widespread human exposure and thus no adequate control group it is virtually impossible to determine a carcinogenic effect by direct observation in man. (EDF v. EPA, 510 F. 2d at 1299; A/D, 39 F.R. 37270; ALJ, 39 F.R. 37254; DDT, 37 F.R. 13371).
6. The use of experiments with animals to test chemicals for carcinogenic hazard to humans is accepted by the scientific community and by public policy-making agencies in the United States. (EDF v. EPA, 510 F. 2d at 1299; A/D, 39 F.R. 37268; ALJ, 39 F.R. 37252).
7. Mice and rats are preferred experimental animal species for carcinogenesis testing because their relatively short lifespan permits lifetime testing covering the entire latency period of tumors within a reasonable time, and because the development of tumors in these species is well known. (EDF v. EPA, 510 F. 2d at 1299-1300; A/D, 39 F.R. 37268; ALJ, 39 F.R. 37252).
8. All chemicals known to cause cancer in man with one exception have been shown to cause cancer in animals, especially mice and rats. (ALJ, 39 F.R. 37252).
9. Pathological development of chemically induced tumors in experimental animals and in humans is very similar. (A/D, 39 F.R. 37268; ALJ, 39 F.R. 37252).
10. Since the number of animals used in laboratory tests is extremely small when compared to the hundreds of millions of people who are involuntarily exposed to widespread chemical contaminants and since the variability of human response to chemical carcinogens is generally greater than that of laboratory animals, a positive oncogenic effect in any test animal is sufficient to characterize the chemical as posing a cancer risk to man and negative results in animal tests have only limited significance and should normally be superseded by positive results. (A/D, 39 F.R. 37272; ALJ, 39 F.R. 37252, 37254).

11. A carcinogenic substance is one which increases benign or malignant tumors or neoplasia in exposed animals; shortens the latency period between the exposure and the development of tumors or neoplasia; or which results in unusual tumors. (EDF v. EPA, 510 F. 2d at 1300; A/D, 39 F.R. 37267; ALJ, 39 F.R. 37255).
12. Since many benign tumors can develop into cancers, for the purposes of carcinogenicity testing there is no valid distinction between the induction of benign or malignant tumors and they should be considered synonymous. (EDF v. EPA, 510 F. 2d at 1300; A/D, 39 F.R. 37267; ALJ, 39 F.R. 37252, 37255).
13. Chemical carcinogenesis is a specific biological process which is induced by a relatively few classes of chemicals. Thus, it is not true that all chemicals induce cancer at sufficiently high doses. (DDT, 39 F.R. 13371; A/D, 39 F.R. 37268; ALJ, 39 F.R. 37252).
14. High doses are administered in animal carcinogenicity tests because limited numbers of animals render the tests relatively insensitive to carcinogenic effects. Consequently, a substance which induces tumors at any dose level represents a warning signal of great significance. (A/D, 39 F.R. 37268; ALJ, 39 F.R. 37254).
15. There is no scientific basis for the existence of a "no effect" level for carcinogens. In principle no dose of a chemical carcinogen is too small to induce tumors in susceptible individuals. (510 F. 2d 1298; A/D, 39 F.R. 37267; ALJ, 39 F.R. 37252).
16. Carcinogens are not specific to particular test species, nor are they specific to certain strains of test species. (A/D, 39 F.R. 37268; ALJ, 39 F.R. 37255-6).
17. Most carcinogens are not organ specific. Thus, a carcinogen which induces liver tumors in mice might, for example, produce mammary tumors in rats and lung tumors in humans. (A/D, 39 F.R. 37268; 39 F.R. 37255-6).

- (1) whether heptachlor and chlordane pose a carcinogenic risk hazard to test animals;
- (2) whether the experimental data derived from the five studies [in the H/C proceeding] can be extrapolated to man; and
- (3) if such extrapolation is possible, whether it is also possible to determine a level of exposure to chlordane and heptachlor which does not pose a health hazard to man.⁶⁸

By so posing the questions, USDA opposed EPA on even more fundamental grounds than did Velsicol. If the validity of introducing animal data is in question, the problem of evaluating the carcinogenic risk of a substance to humans is a far more difficult one. (The National Agricultural Chemicals Association later intervened in support of USDA's motion.)

Velsicol moved to reconsider its earlier motion for referral to NAS and proposed an alternative motion in the event the earlier motion was not reconsidered. The alternative proposal by Velsicol was to refer the following questions to NAS:

- (1) Whether a chemical which induces benign tumors in a test animal at any level of exposure is a carcinogen.
- (2) Whether a threshold exposure level may be determined for a carcinogenic agent.
- (3) Whether the five cancer studies...demonstrate a carcinogenic effect in the treated animals.
- (4) If any of these five cancer studies are carcinogenic to the test animal [sic], whether these results may be extrapolated to man.
- (5) If these results may be extrapolated to man, whether at current levels of exposure, heptachlor and/or chlordane pose a carcinogenic risk to man.⁶⁹

As was the case for Velsicol's earlier motion, USDA supported it, and EPA and the Environmental Defense Fund (EDF) opposed it. The same issues were in contention. According to the ALJ, they were:

...the significance of the concept of a 'threshold' exposure level to a carcinogenic agent and the characterization of the chemical which induces benign tumors as a carcinogen....⁷⁰

Both Velsicol's and USDA's motions were denied. In a brief⁷¹ opposing official notice of EPA's 38 facts, Velsicol commented point-by-point on all 38. With one exception, these comments were not supported by documentation. A number of points raised by Velsicol's comments are similar to those widely discussed in conjunction with the principles and, therefore, serve to highlight the debate and confusion over the validity and the use of the principles. Each comment selected is followed by the number of the principle to which it is directed (see Table 3). They appear to fall into four broad categories.

1. Magnitude of the Cancer Problem

-- if respiratory cancer, which is linked in large part to smoking, is considered separately, cancer incidence appears to be declining at any age (no. 1).

-- the average age of people who die of cancer is very close to the average age of people dying from other causes (no. 1).

2. Uncertainty in the Mechanism of Cancer Induction

-- a carcinogen induces malignant tumors (no. 11); in humans it is rare for a benign tumor to transform to malignancy (no. 12).

-- there is a "no-effect" level for all toxicants, and carcinogens have not been demonstrated to be different (no. 15).

-- carcinogens exhibit dose-response and dose-time relationships, and since the latency period is dose dependent, a small exposure level may lead to a latency period which extends beyond the life expectancy of the population (no. 3).

-- it is not known how or why spontaneous tumors arise in certain animal species (no. 7).

-- although the pathology of cancer is similar between species, biochemical (or metabolic) differences suggest that development of cancer is not necessarily similar (no. 9).

3. Establishment of Carcinogenicity and Assessment of Risk

-- the variability of human response compared to animals is conjecture (no. 10).

-- it is possible to identify adequate control groups for epidemiological studies (those exposed to a substance in a particular group can be compared to those in a comparable group prior to introduction of the substance) and thereby to use direct observation in man to enable assessment of cancer risk (no. 5).

-- although animal experiments have to be used in evaluating cancer risk, whether each species is useful to predict hazard is widely questioned (no. 6).

-- the evaluation of risk by assessing exposure should include an analysis of the dose level, time and route of exposure, and the identity and characteristics of the specific chemical agent (no. 1).

4. Problems with Experiments in Animals

-- a positive oncogenic (tumor producing) effect in any animal test is not sufficient to characterize a substance as posing a risk of cancer. Negative responses are important for determining no-effect levels or dose-response relationships (no. 10).

-- although high doses can emphasize potential effects, experiments at low doses are necessary to establish dose-response relationships with thresholds. Also, high dose runs can confuse damage induced by other toxic effects with tumorigenic effects (no. 14).

-- all stresses known to induce cancer in mice that are inbred and susceptible are not deemed carcinogenic in man (no. 8).

These comments were designed to suggest that there is sufficient controversy or uncertainty associated with the 17 cancer principles to prevent them from being officially noticed as consensus points among cancer experts. Such an approach implies that unanimity (or very close to it) is necessary among scientists before regulatory actions to prevent exposure to carcinogens can be taken. Unanimity is an impossible standard to achieve in an uncertain area of knowledge.

The principles were developed originally by expert committees to make explicit reasonable presumptions concerning the evaluation of carcinogenicity data. To highlight the uncertainties of cancer without fully addressing the presumptions underlying them is to ignore their intent. Many of the comments by Velsicol imply that the burden of proof should not fall on the registrants of the pesticides to show the absence of "unreasonable adverse

effects," as required by FIFRA, but rather should rest with the Agency to demonstrate harm.

When the principles were distributed among various scientists unfamiliar with the history of efforts to develop principles, they seemed to be arbitrary in that they were referenced to the Federal Register and various court decisions and not to scientific publications. This further fueled the controversy, and the scientists who disagreed with the principles (since they were not unanimously supported) appeared to be in the majority.

The cancellation proceeding was interrupted by the Administrator's issuance of a notice of intent to suspend registration of certain Heptachlor and Chlordane pesticide formulations.⁷² The notice was based on a finding of "imminent hazard":

New evidence has recently come to my attention which confirms and heightens the human cancer hazard posed by these pesticides. It is apparent that the ongoing cancellation proceedings would not be concluded in time to avert substantial additions of these persistent and ubiquitous compounds to already serious human and environmental burdens.⁷³

In the notice, he discussed the new evidence,⁷⁴ and recent reinterpretations by independent pathologists of the slides from existing studies, and then cited the findings of the Courts of Appeals in the A/D and DDT decisions that:

...the function of the suspension decision is to make a preliminary assessment of evidence and probabilities, not an ultimate resolution of difficult issues. We cannot accept the proposition...that the Administrator's findings [are] insufficient because controverted by respectable scientific authority. It...[is] enough that the administrative record contain respectable scientific authority supporting the Administrator.⁷⁵

The Administrator then said:

As I have repeatedly stated [references omitted], after extensive EPA experience in evaluating the cancer hazard of pesticides, we do not begin our evaluation of the cancer threat of heptachlor/chlordane in a vacuum. In my prior orders relating to DDT and Aldrin/Dieldrin, and in the Preamble to the FIFRA registration regulations, I have set forth the basis for evaluating the carcinogenicity of pesticides which I am applying in evaluating the cancer hazard posed by the use of

heptachlor and chlordane for the purposes of this suspension notice and which shall be applied to evaluate that hazard in an expedited suspension hearing, if a hearing is requested.⁷⁶

The notice contained a discussion of the principles and policy for evaluating carcinogenesis, which insured adoption of the cancer principles in the suspension proceeding. There the 38 facts introduced during the cancellation proceeding were officially noticed in the suspension proceeding by the ALJ. Velsicol vigorously contested this:

...the Administrator...directs that certain scientific standards [the principles and policies for evaluating carcinogenicity] be applied and permit no evidentiary challenge to their validity....⁷⁷

The Agency responded by issuing a clarification, in which it was explained that evaluating the carcinogenicity of pesticides in the notice of intent to suspend "...was not intended to foreclose registrants or other parties from introducing evidence in challenge to the basis for evaluation."⁷⁸

Early in the suspension proceeding, Saffiotti sent a revised version of the 17 cancer principles (a "draft for discussion") to EPA. This version (see Table 4) was introduced in the H/C suspension proceeding in addition to EPA's first version of 17 principles. Saffiotti said at the beginning of his "draft for discussion" that:

Principles of carcinogenesis have been extensively discussed and reported by several national and international committees of scientifically qualified experts. Key references are attached. It is necessary to view the following statements in light of such reports and to consider them as summary statements.⁷⁹

Saffiotti and Jeffrey H. Howard, former EPA Associate General Counsel for Pesticides, Toxic Substances, and Solid Waste Management, had reviewed the 9 principles from A/D and expanded them into 17. At Howard's request, Saffiotti forwarded them to EPA. These 17 principles were based, as were the first set of 17, on the language in previous decisions of the Administrators and the ALJs in the DDT and A/D cases. In his letter to Howard, Saffiotti said:

You indicated to me that these statements were originally drawn by the legal staff at EPA in summarizing very detailed testimonies which extended over several days of cross-examination. As reminders of points of discussion...they serve

TABLE 4

CANCER PRINCIPLES REVISED BY UMBERTO SAFFIOTTI, AUGUST 25, 1975

Draft For Discussion

STATEMENTS ON PRINCIPLES OF CHEMICAL CARCINOGENESIS
IN RELATION TO THE EVALUATION OF CARCINOGENIC HAZARDS

Umberto Saffiotti, M.D.

Principles of carcinogenesis have been extensively discussed and reported by several national and international committees of scientifically qualified experts. Key references are attached. It is necessary to view the following statements in the light of such reports and to consider them as summary statements.

1. Cancer is the second largest cause of death in the United States and its incidence is still increasing. It imposes upon society an immense burden of death, suffering, and economic loss.
2. The majority of human cancers are believed to be caused by exposure to extrinsic carcinogenic factors which include physical and chemical agents, many of which are avoidable.
3. Chemical carcinogenesis is characterized by a long latency period which in humans can be as long as 30 years or more between the initial exposure and the appearance of symptoms of the disease.
4. A chemical carcinogen is any substance which has been shown to cause tumors in adequately conducted studies in man or in animals. A critical evaluation of the relevant studies, both qualitative and quantitative, is needed in order to establish this causal relationship, which may be evidenced by significantly increased incidences of tumors and/or by shortening the latency period between the exposure and the development of tumors.
5. Any substance which has been shown to cause tumors in any mammalian species in adequately conducted studies at any dose level must be considered a carcinogenic hazard to humans, unless proven otherwise.
6. Chemical carcinogenesis appears to be a specific biological process, induced by chemicals which can undergo certain chemical reactions with cellular target macromolecules. It is not true that all chemicals cause cancer even at maximum doses of administration.
7. Carcinogenesis and mutagenesis are characterized by a self-replicating irreversible cellular change. The natural history of neoplasms, with few exceptions, is to grow irreversibly.

8. All chemicals presently known to cause cancer in man (with the exception of arsenic) have been also shown to cause cancer in animals. Most of this evidence is derived from bioassays in rodents.
9. Pathological development of chemically-induced tumors in experimental animals and in humans is very similar and most of the major types of cancer seen in human pathology can be reproduced in animals by chemical induction.
10. The long latency period of cancer, its frequency in the population, and the difficulty in characterizing chemical exposures in populations and in identifying control groups which are not exposed to certain chemicals hinders epidemiological research. With chemicals to which exposure is nearly ubiquitous in the population, it is extremely difficult if not impossible to detect a specific carcinogenic effect in the population.
11. The use of animal experiments to test chemicals for potential carcinogenic hazard to humans has been so far the only method accepted by the scientific community as reliable and adopted by public policy-making agencies in the United States. Short-term methods for the induction of neoplastic transformation of cells in culture presently show great promise as predictive screening tests but are not yet sufficiently validated.
12. Mice, rats, and hamsters are the experimental animal species of choice for carcinogenesis testing because their relatively short lifespan permits lifetime testing within a period of two to three years, and because tumor pathology in these species is well known.
13. Chemical carcinogens do not appear to be specific in their effect only for one animal species. When extensively studied in different species of laboratory animals, chemicals which are carcinogenic in one species usually appear to be also active in others. The organs and tumor types involved in the carcinogenic response may not be the same under different test conditions, or in other strains, or in other species (including humans).
14. The human population is genetically highly heterogeneous and therefore likely to have much more individual variability in susceptibility than laboratory animal populations, which are obtained from closed breeding colonies or even selectively inbred. It is the population subgroup more highly susceptible to carcinogens that requires the highest level of environmental protection.
15. Current bioassay protocols for long-term carcinogenesis bioassays on animals are relatively insensitive, since they are usually designed to detect only levels of tumor induction higher than 5% or 10%. Negative results obtained in such tests are grossly inadequate to give assurance of safety for humans. Chemicals that are detected as positive in such tests are therefore, in this sense, "strong" carcinogens.
16. No method is known for establishing a no-effect level of exposure to a carcinogen for humans.
17. The implication of carcinogenicity should be drawn both from tests resulting in tumors diagnosed as benign and from those resulting in tumors which are more obviously malignant for the following reasons:
 - a. When adequately studied, virtually no chemicals are known to cause exclusively benign tumors and never to cause malignant tumors.

- b. Many benign tumors may become malignant and there is evidence that in many cases the induction of histologically benign tumors is merely a stage in the induction of malignancy.
- c. Benign tumors can pose serious health risks as such, even without becoming malignant.
- d. If the exclusively benign nature of the tumor response were to be established, in most cases extensive microscopic analysis should be undertaken to rule out the presence of metastatic spread by multiple sections of all tissues which could be reached by tumor cells migrating from the primary tumor.

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their purpose in indicating the key issues involved in carcinogenesis evaluations. The nine statements are, however, quite inadequate if taken out of context.... After more than twenty years of research activities involving the need to express recommendations on principles of carcinogenesis based on current scientific evidence.... I am well aware of the difficulties of reducing a long discussion of a complex problem to a few short summary sentences, particularly if they have to be used in isolation from an explanatory context.⁸⁰

Saffiotti became a center of controversy. His name appeared prominently on his draft of the 17 principles. Widespread distribution of that document (frequently without the key references), recognition of the importance of his testimony in the DDT, A/D, and H/C cases, articles in several trade magazines,⁸¹ and the involvement of the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board (as shall be discussed later) all contributed to the criticism directed at Saffiotti.

The recommended decision of the ALJ in the H/C suspension proceeding⁸² was to dismiss the notice of intention to suspend:

Much of the initial controversy herein turns on the results of the review of slides of basically the rodent liver by pathologists.... But, it appears to us that some of the divergence demonstrated is, in reality, a matter of semantics or nomenclature rather than substance.⁸³

For the studies completed prior to the suspension proceeding, the original five pathologists interpreted them as showing no carcinogenicity, and EPA used six independent pathologists to reinterpret the slides, and Velsicci used seven. All but two of these thirteen independent pathologists agreed that there was evidence of carcinogenicity. The two who disagreed based their judgment on the apparent absence of metastasis (spread of cancer cells to remote organ sites) or invasion of adjacent tissue. The ALJ believed that their appraisals could not be disregarded, nor could he

...state that they are necessarily in error or employ improper criteria. In reality, we do not feel competent to do so.⁸⁴

The ALJ first cited a previous court decision that stated the following as an acceptable criterion of carcinogenicity:

...mice under experimental exposure...[develop]
tumors with 'malignant potentiality.'⁸⁵

and then contrasted this with an early working draft of a report of the Subcommittee at NCI which was introduced into the record by Velsicol. The Subcommittee draft stated:

...a carcinogen is defined as a substance which when administered to groups of animals results in reproducible increases in incidence of malignant neoplasms [tumors] in the treated groups when compared to control groups....⁸⁶

This definition was substantially altered in the final report of the Subcommittee, whose work is discussed below in the section on peer review. The ALJ then stated:

By reason of the foregoing, we conclude that heptachlor and its metabolite appear to be a carcinogen in the mouse...and may be a carcinogen in the...rat...and that chlordane appears to be a carcinogen in the mouse.... In other words, we are hesitantly unwilling at this time to find that heptachlor and chlordane are conclusively carcinogens in laboratory animals.⁸⁷

In a footnote to the above statement, he wrote:

The Administrator could perhaps...[find the pesticides to be carcinogens] on the basis of this record.⁸⁸

The Administrator overruled the ALJ's recommended decision. All of the ALJ's findings were adopted, but the Administrator stated that:

[i]n partially rejecting Judge Perlman's recommended conclusions, I have in most instances substantially agreed with his assessment of the facts. The partial reversal results almost completely from the application of rules of law laid down by the FIFRA itself and by judicial decisions interpreting it....⁸⁹

The Administrator argued that it is not necessary to conclude that actual harm to man will occur if use of the pesticide in question is continued. Even if evidence on risks or benefits is incomplete, or is expected to be developed in the cancellation proceeding, that is not sufficient to deny suspension. Therefore, the finding that H/C appear to be carcinogens in laboratory animals meets the standards of the statutes and controlling decisions. The Administrator noted:

It is generally not possible to obtain sufficient information to determine whether particular substances that are widespread in the environment in small amounts cause cancer in man.⁹⁰

and wrote:

In view of the Agency's developed experience and knowledge in this area, the notice of intent to suspend (together with the clarifying order of August 6) provided a statement of the principles and policy that would be applied in this proceeding. The record in this proceeding confirms the correctness of these principles [reference omitted].⁹¹

Widespread misunderstanding of the principles and considerable controversy over their use in this and other proceedings reached such a peak that EPA withdrew the motion for official notice of the principles in the H/C cancellation proceeding on April 27, 1976. This was shortly after the suspension decision was argued before the U.S. Court of Appeals for the District of Columbia Circuit, whose decision was rendered on November 10, 1976. The decision affirmed the suspension order and the Administrator's conclusion:

...that the ALJ had applied an erroneous legal standard in requiring a conclusive, rather than probable, showing that the pesticides were animal carcinogens....⁹²

The court rejected:

Velsicol's argument that the 'cancer principles' EPA relied on in structuring its analysis of the mice and rat studies improperly biased the Agency's open-minded consideration of the evidence.... [The principles] form part of the Agency's 'scientific expertise'.... EPA's specific enunciation of its underlying analytic principles, derived from its experience in the area, yields meaningful notice and dialogue, enhances the administrative process and furthers reasoned Agency decision making.⁹³

The court also discussed Velsicol's contention that objective evidence of carcinogenicity was lacking because the tumors observed did not show metastasis or invasion, which

two of their witnesses considered essential definitional elements of 'cancer.' By contrast, the other pathologists consulted...generally believe that cancer can be reliably diagnosed by

observation of tissue cells under a microscope...without evidence, or very much evidence, of invasion and metastasis.⁹⁴

The court added that examination techniques developed since the original studies were more sensitive, and therefore, explained some of the failure in earlier studies to observe metastasis and invasion.

The Administrator issued the notice of intent to cancel on November 18, 1974. In June 1976, the cancellation proceeding resumed and is likely to continue until September 1977. Additional efforts by Velsicol and USDA to refer the question of the carcinogenicity of H/C to a committee of the NAS scientists were successful, and the referral was sent to NAS on June 15, 1977.

G. Use of Cancer Principles in the Mirex Fact-Finding Proceeding

Cancer principles were also introduced in the Mirex fact-finding proceeding. Putatively, the fact-finding procedure is used to compile information that will permit the Administrator to reach a decision on whether to issue a notice of intent to cancel. The Mirex proceeding continued for over three years before an agreement was reached between the Allied Chemical Corporation, the principal registrant, and EPA. If the carcinogenicity issue is an indication of the way other issues are treated, there is no significant difference between fact-finding and cancellation proceedings.

As in the H/C suspension proceeding, numerous efforts were made to refer the issue of the carcinogenicity of Mirex to a committee of NAS scientists. One such motion proposed by USDA in August 1975 was supported by Allied, three agricultural and trade associations, nine state agricultural departments, and three individuals. EPA, the Environmental Defense Fund, six local and four other national environmental groups opposed the motion. In all, there were 672 witnesses.⁹⁵ The ALJ denied this and other motions to refer questions of carcinogenicity to NAS.

EPA moved⁹⁶ to have a version of 17 cancer principles officially noticed and incorporated in the record of the proceeding (see Table 5). This version closely resembled the version submitted by Saffiotti as a "draft for discussion," which was later introduced by EPA,⁹⁷ and the first set of 17 principles from the H/C proceeding. Both the Allied Chemical Corporation and USDA vigorously opposed official notice of the principles, and the ALJ for this proceeding denied the motion for official notice.⁹⁸

TABLE 5

CANCER PRINCIPLES FROM EPA'S MOTION TO TAKE OFFICIAL NOTICE
IN THE MIREX FACT-FINDING PROCEEDING, SEPTEMBER 9, 1975

1. Cancer is the second largest cause of death in the United States and its incidence is still increasing. It imposes upon society an immense burden of death, suffering, and economic loss. See Recommended Decision, In re: Shell Chemical Co., FIFRA Docket No. 145, et al., 23 (hereinafter cited as ALJ), 39 F.R. 37252.
2. The majority of human cancers are believed to be caused by exposure to extrinsic carcinogenic factors which include physical and chemical agents, many of which are avoidable. See Opinion of the Administrator, In re: Shell Chemical Co., FIFRA Docket No. 145, et al., (hereinafter cited as A/D), 39 F.R. 37267.
3. Chemical carcinogenesis is characterized by a long latency period which in humans may be as long as 30 years or more between initial exposure and the appearance of symptoms of the disease. See EDF v. EPA, 510 F.2d at 1299; A/D, 39 F.R. 37270; ALJ, 39 F.R. 37252.
4. A chemical carcinogen is any agent which has been shown to cause benign or malignant tumors in adequately conducted studies in man or in animals. Critical quantitative and qualitative evaluation is necessary to establish this causal effect which may be evidenced by significantly increased tumors or by shortening the latency period between the exposure and the development of tumors, or by the development of unusual tumor types. See EDF v. EPA, 510 F.2d at 1300; A/D, 39 F.R. 37267; ALJ, 39 F.R. 37255.
5. Any substance which has been shown to cause tumors in any mammalian species in adequately conducted studies at any dose level must be considered a carcinogenic hazard to humans, unless proven otherwise. See A/D, 39 F.R. 37272; ALJ, 39 F.R. 37252, 37254.
6. It is not true that all chemicals cause cancer even at maximum doses of administration. Chemical carcinogenesis appears to be a specific biological process, induced by chemicals which undergo chemical reactions with cellular target macromolecules. See DDT, 37 F.R. 13371; A/D, 39 F.R. 37268; ALJ, 39 F.R. 37252.
7. Carcinogenesis and mutagenesis are characterized by self-replicating irreversible cellular change. The natural history of neoplasms is to grow irreversibly. See EDF v. EPA, 510 F.2d at 1298; ALJ, 39 F.R. 37252.
8. All chemicals known to cause cancer in man with the exception of arsenic have been shown to cause cancer in animals, especially mice and rats. See ALJ, 39 F.R. 37252.
9. Pathological development of chemically-induced tumors in experimental animals and in humans is very similar and most of the major types of cancer seen in human pathology can be produced in animals by chemical induction. See A/D, 39 F.R. 37268; ALJ, 39 F.R. 37252.

10. The long latency period of cancer, its frequency in the population and the difficulty in isolating control groups which are not exposed to certain chemicals hinders epidemiological research. With chemicals to which exposure is widespread in the population, it is extremely difficult if not impossible to detect a specific carcinogenic effect in the human population. See EDF v. EPA, 510 F.2d at 1299; A/D, 39 F.R. 37270; ALJ, 39 F.R. 37254; DDT, 37 F.R. 13371.
11. The use of experiments with animals to test chemicals for potential carcinogenic hazard to humans has been so far the only method accepted by the scientific community as reliable and adopted by public policy-making agencies in the United States. See EDF v. EPA, 510 F.2d at 1299; A/D, 39 F.R. 37268; ALJ, 39 F.R. 37252
12. Mice, rats and hamsters are preferred experimental animal species for carcinogenesis testing because their relatively short life-span permits lifetime testing within a reasonable time, and because tumor pathology in these species is well known. See EDF v. EPA, 510 F.2d at 1299-1300; A/D, 39 F.R. 37268; ALJ, 39 F.R. 37252.
13. Chemical carcinogens do not appear to be specific in their effect only for one animal species. When extensively studied in different species of laboratory animals, chemicals which are carcinogenic in one species usually appear to be active in other species as well. The organs and tumor types involved in the carcinogenic response may not be the same under different test conditions, or in other strains or in other species (including humans). See A/D, 39 F.R. 37268; ALJ, 39 F.R. 37255-6.
14. The human population is genetically highly heterogeneous and therefore likely to have much more individual variability in susceptibility than laboratory animal populations which are usually obtained from closed breeding colonies or even selectively inbred. Thus some humans are likely to be more susceptible to carcinogens than laboratory animals. See A/D, 39 F.R. 37269; ALJ, 39 F.R. 37252, 37254.
15. Current bioassay protocols for long-term carcinogenesis bioassays in animals are relatively insensitive, since they are usually designed to detect levels of tumor induction higher than 5% or 10%. Negative results obtained in such tests are grossly inadequate to give assurance of safety for humans. Chemicals that are detected as positive in such tests are therefore, in this sense, "strong" carcinogens. See ALJ, 39 F.R. 37254.
16. There is no method for establishing a "no-effect" level for human exposure to carcinogens. See EDF v. EPA, 510 F.2d at 1298; A/D, 39 F.R. 37267; ALJ, 39 F.R. 37252.
17. The implication of carcinogenicity should be drawn both from tests resulting in tumors diagnosed as benign and from tests resulting in tumors which are more obviously malignant for the following reasons:
 - a. Many benign tumors become malignant and there is evidence that in many cases the induction of benign tumors is merely a stage in the induction of malignancy.
 - b. When adequately studied, virtually no chemicals are known to cause exclusively benign tumors and not cause malignant tumors.

c. Benign tumors pose serious health risks even without malignancy.

d. If the exclusively benign nature of the response were to be established, in most cases, extensive microscopic analysis should be undertaken to rule out the presence of metastatic spread. This examination would require multiple sections of all tissues which could be reached by tumor cells migrating from the primary tumor. See EDF v. EPA, 510 F.2d at 1300 n.21; A/D, 39 F.R. 37267; ALJ, 39 F.R. 37252, 37255.

A number of factors probably led to this denial of the motion to take official notice of the cancer principles. The most important is that the controversy over the use of the cancer principles had highlighted the uncertainties in evaluating carcinogenicity. Considerable documentation was presented to support the principles, but USDA and Allied presented virtually every conceivable argument against them. This opposition created the impression that the concepts embodied in the principles were widely disputed, and the ALJ for this proceeding apparently didn't believe that the NAS was the appropriate forum for resolving the dispute.

Many of the arguments against the principles were directed at the use of citations from the Federal Register and court decisions. Saffiotti's version contained references to reports of scientific advisory committees and scientific papers, but criticism also was directed at the specific language of the principles. One brief submitted by USDA in opposition to the motion for official notice of the principles compares the language of each principle to the language in the orders or decisions on which they are based:

...[Because] the findings or positions expressed in the cited passages have been extensively restated and supplemented...[the]...principles have not been accepted or approved in their present form by the Administrator...."

Therefore, it was argued, EPA's claim that the principles have been adopted by the Administrator and upheld by U.S. Courts of Appeals is incorrect. [It is the author's view that the meaning or substance of the 17 principles is not significantly altered from that of the orders and decisions.]

The early drafts of the report of the NCI Subcommittee on Environmental Carcinogenesis were cited often in criticism of the principles. The drafts were claimed to demonstrate the invalidity of the principles, or at least the claim of their being "...the most advanced research findings and policy of both national and international experts and agencies...." As shall be discussed, the final version of the Subcommittee's report incorporated most of the concepts embodied in the principles.

Once the motion for official notice was denied in the Mirex fact-finding proceeding, the Agency moved for reconsideration of the denial, which was also denied. In the motion for reconsideration, EPA sought official notice of three basic facts:

- (1) There is presently no scientific basis for concluding that there is a 'no effect' level for chemical carcinogens.

(2) Experimental data derived from mouse and rat studies can be used to evaluate whether there is a cancer risk to man.

(3) All tumorigens must be regarded as potential carcinogens. For purposes of evaluating carcinogenicity hazard, no distinction should be made between the induction of tumors diagnosed as benign and the induction of tumors diagnosed as malignant.¹⁰⁰

Official notice of these principles was denied¹⁰¹ and was not sought further. In an affirmation of the ALJ's denial of the motion to take official notice, the Administrator said:

...I must emphasize that my decision today should not be construed as a signal that I am wavering in the slightest degree from my prior FIFRA decisions in which principles basically akin to Respondent's proposed 'facts' were relied upon [reference omitted]. Based upon the accumulating body of Agency expertise in this area, I remain convinced that Respondent's proposed 'facts' are valid principles [the Administrator cited one reservation about the second of the three basic principles; reference omitted] to support regulatory and adjudicatory actions under a public health statute such as FIFRA [reference omitted].¹⁰²

The Administrator's reservation was:

In my view, this is a valid principle to the extent it means that distinctions between malignant and benign tumors should not be made in determining whether there is a cancer hazard to man; I question the sentence's validity, however, if it means that in reaching my ultimate conclusions as to whether and to what extent I would cancel a pesticide, I have no authority to make distinctions between evidence of benign and malignant tumors.¹⁰³

This is a revealing statement on the relationship between the principles and the analysis of experimental evidence. It illustrates the difference between the framework or criteria for risk analysis and the estimation of the level of risk. Diagnoses of benign and malignant tumors are to be considered in determining whether a substance poses a carcinogenic risk, but the state of malignancy and the history of the specific tumor-type in question would be considered in estimating the level of risk, against which the benefits of use are balanced.

H. Use of Cancer Principles in Rule Making

The cancer principles were indirectly cited in the preamble to the Agency's regulations for registration, reregistration, and classification of pesticides.¹⁰⁴ Criticism of the cancer principles used in the H/C and Mirex proceedings often was fueled by charges that the cancer principles were to be used as a checklist for registration decisions by EPA without benefit of scientific review and analysis and the Agency's pesticide regulations were often cited.

Individual points covered in the cancer principles, although reworded, are discussed in various parts of the preamble to the regulations. In the regulations, the Agency states:

In determining the factors and criteria for initiating a cancellation or denial proceeding because of 'unreasonable adverse effects on the environment' and for issuing final orders in such proceedings, the Administrator has been guided by the general principles and policies developed in previous cancellation and suspension proceedings which have been affirmed by United States Courts of Appeals.¹⁰⁵

Thus, the decisions of the Administrator in the DDT cancellation proceeding, the A/D suspension proceeding, the request for exemption for use of DDT, and the DDT and A/D decisions of the United States Courts of Appeals are the cancer policy and principles of the Agency to which the regulations refer.

Part of the confusion regarding the use of the cancer principles may be due to the following statement in the preamble:

In accordance with the principles of hazard evaluation in the exhaustive DDT and Aldrin/Dieldrin administrative and court proceedings, the use of animal test data is the foundation for hazard evaluation criteria for new and old pesticide products. Such data are used to evaluate both the short term and the long term effects from the use of a pesticide; therefore...both acute and chronic effects criteria are set forth.¹⁰⁶

This statement, when seen in light of the section of the preamble in which the criteria for chronic testing are discussed, further clarifies the origin of the misunderstanding. A subsection describes a new plan for hazard evaluation. The plan provides for screening criteria

that can trigger a presumption against registration or reregistration of a pesticide, which may be rebutted by the applicant (a rebuttable presumption against registration, or RPAR). An RPAR arises if a pesticide induces oncogenic (tumor-inducing) or mutagenic effects. The Agency states:

With respect to oncogenic effects, this criterion incorporates the policy and principles established in the DDT cancellation proceeding and the Aldrin/Dieldrin suspension proceeding.¹⁰⁷

The idea of an automatic trigger based on criteria that incorporate principles of carcinogenicity seems to have been a source of widespread misunderstanding. The underlying philosophy of such a trigger is not unreasonable when it is recognized that the RPAR procedure is a screening technique and not the means for determining the final outcome of a registration decision. Hence, if the use of a pesticide is accompanied by low risk, the sale and distribution of the pesticide is of much less concern to EPA than a pesticide for which evidence exists of serious risk and for which a careful examination of benefits is necessary to justify the risk. The RPAR procedures flag the pesticides for which evidence exists of serious risk and for which a careful look at benefits is needed. A risk/benefit determination is part of the procedure, but the outcome is not automatic.

Another element in the controversy over the principles was the split between the Office of General Counsel (OGC) and the Office of Pesticide Programs (OPP). Fundamental differences existed between the opinions of the cancer experts and the reports upon which the OGC relied and the views of scientists in OPP. For example, recent reports¹⁰⁸ disclosed a plan developed by a former head of the criteria and evaluation division, Leonard Axelrod, and the chief of the metabolics branch, Lamar B. Dale, in OPP to fund a test in humans of a fungicide known to induce cancer in animals. The OPP scientists actively pursued the project with an academic scientist, Wayland J. Hayes, and the Rohm and Haas Co., the manufacturer of the fungicide EBDC. The proposal first involved the use of prisoners to test the chemical, then students in nursing schools, medical schools, and the paramedical profession, and eventually settled with tests on Mexican citizens. The head of OPP stopped the project after Howard (while he was in OGC) protested strongly. As explained earlier, tests on humans of pesticide or food chemicals (as opposed to drugs) were considered unethical and impractical by expert committees.

The views of Axelrod and Dale are representative of an extreme, but the views of many OPP scientists were generally along the lines of those in industry and USDA, who felt, for example, that evidence of advanced stages of malignancy were necessary to characterize tumors as carcinogenic. Also,

many scientists in OPP had extensive toxicological experience in industry, USDA, or FDA with substances that induce reversible effects below a certain "threshold" of action. Thus, they believed "no-effect" levels should be set for carcinogens as they are for substances posing acute and certain other chronic hazards. Furthermore, many in OPP believed rodents (mice especially) were inappropriate animal models for cancer testing.

Because cancer is such a poorly understood disease, there are no unequivocal answers to a great many questions. The principles were an attempt to summarize reasonable presumptions concerning the design and interpretation of studies to detect carcinogens. They sought to present in simple terms the thinking of expert committees that had addressed the problems of carcinogenicity testing for over 25 years. Not surprisingly, many scientists in OPP opposed the use of the principles, and OGC took the lead in preparing the scientific and technical basis for the Agency's position on carcinogenicity in cancellation actions. Under other circumstances, OPP would have had a large hand in the cancer issue during cancellation actions; OPP and other Agency scientists testified on many issues other than cancer.

I. Origins of the Cancer Principles¹⁰⁹

Although it is not the intention in this case study to evaluate the scientific validity of the cancer principles, it seems appropriate to examine in detail some of the underlying documentation. For this reason, some of the reports and articles that were entered into the record of various fact-finding, cancellation, and suspension proceedings, and that form the basis for the principles will be discussed. The following discussion is intended to illustrate the surprising consensus--short of unanimity--on the concepts embodied in the cancer principles and is limited to four such concepts:

-- It is necessary to extrapolate from animal studies, particularly in rodent species, to humans in order to evaluate the risk of cancer.

-- Not all chemicals are capable of causing cancer, even at maximum doses of administration.

-- Although a distinction can frequently be made between benign and malignant tumors, for the purposes of establishing the carcinogenicity of a substance, they should be considered synonymous.

-- There is no practical method for determining a "no-effect" or threshold exposure level in humans for carcinogens.

1. Extrapolation from Rodents to Humans

The first issue of reliance on studies in rodents has already been discussed earlier to some extent. It should be recalled that the various expert committees agree that reliance on animal studies is necessary because of the practical and ethical limitations in reliance on epidemiological studies to identify carcinogenic agents and because of the evidence of the validity of studies in experimental animals as the basis for establishing the carcinogenicity of a substance.

Discussions by expert committees of the optimal conditions for carcinogenicity testing has included consideration of appropriate mammalian species for testing. After a thorough review of carcinogenicity testing, the Mraz Commission reported in 1969:

The species most practical for testing are rats, mice, and--as more recently shown--hamsters. Strains and colonies should be selected to provide adequate sensitivity to tumor induction, as revealed by positive control tests with known carcinogens.... The use of nonrodent species, recommended in the earlier reports, has now been substantially dropped. A suitable, practical nonrodent species would be useful but it is not available at this time.... While dogs have been employed for tests of carcinogenicity, with noteworthy success in selected cases (bladder carcinogenicity of aromatic amines), the requirement of lifetime feeding makes this species too expensive, in terms of time and funds, to be employed routinely. 110

Again in 1975, an NRC committee confirmed the views expressed in many of the earlier reports:

Rodents are the animal of choice for carcinogenesis tests because of their convenience, comparatively short life span and proven susceptibility to a broad range of carcinogenic agents. 111

Another NRC report published in 1975 concluded:

...the carcinogenic risks, and other health hazards, of pesticides require continuing evaluation by testing with laboratory mammals; and...despite the problems involved in translating

and results from such experiments to human risk, the present techniques are sufficiently reliable to justify registration actions based upon such data alone, on an interim basis, until evidence convincingly demonstrates that there is no human risk.

This conclusion was based on tabulations of the correlation between agents known to cause cancer in man and also studied in animals and of the estimated correspondence between exposure levels:

Notwithstanding the difficulty of identifying specific carcinogens affecting man, about a dozen agents are now recognized as human carcinogens. All of these but one are definitely carcinogenic in tests on laboratory animals.... The only exception is arsenic, which is still under test on animals. It may be noted that the organs affected in man are not always the same as those that are found to develop tumors in laboratory animals, nor is the organ specificity the same in different species of rodents. Nevertheless, the evidence, based on a limited number of carcinogens, suggests that most agents that pose a carcinogenic threat to man will be carcinogenic in laboratory tests on animals.¹¹²

The uncertainties in extrapolation to man from studies in animals have long been recognized. The Mark Commission noted:

...it is of utmost importance that the results of screening tests be scientifically and rationally considered. The correct interpretation of hazards to human health is sometimes extraordinarily difficult. It must involve the transfer of the results of animal experiments to prediction of human effects. In addition, the screening process frequently involves preliminary examination of the effects of massive dosages, possible contamination of samples, and other factors which affect proper interpretation...[but]...[t]he health and welfare of the public must be effectively protected.¹¹³

The NCI Subcommittee on Environmental Carcinogenesis also discussed the uncertainties in extrapolation and concluded:

Because of the limitations inherent in animal bioassays, a negative result obtained in a particular animal bioassay does not exclude the potential carcinogenicity of a compound in humans. The inappropriate experimental species may have been chosen; the number of animals tested may have been too small; or the duration of observation may

have been inappropriate in terms of their predictive value for the response of humans. The extrapolation of experimental carcinogenicity data to the human situation is strengthened by obtaining results in more than one species. Negative results obtained in one species do not, however, detract from the significance of clear positive results obtained in another species.¹¹⁴

In the A/D and H/C proceedings, carcinogenicity data in mice were the principal, if not the exclusive, evidence upon which the inference of risk of cancer in humans was drawn. The concern by Shell and USDA over uncertainties in such an extrapolation involved the predictive value of liver tumors in mice for human cancer. Although most carcinogens are not organ-specific (mammary tumors in rats may be induced by an agent known to induce bladder cancer in man), the occurrence of liver tumors in mice was attributed to the sensitivity and unique metabolic properties of the mouse liver. However, a survey of 58 compounds known to induce liver tumors in mice tends to affirm its predictive value:

A positive correlation appears to exist between the capacity of a chemical to induce liver tumors in the mouse and its capacity to induce tumours at any site in the rat or the hamster.¹¹⁵

2. Can All Chemicals Cause Cancer?

The concern with the sensitivity of mice has contributed to the idea that all chemicals are capable of causing cancer if administered to experimental animals at sufficiently high doses. Recently, substances representing a wide range of chemical structures and used for a variety of purposes have been found to be carcinogenic. These findings have also encouraged this belief. This belief appears to be based on a concept of carcinogenesis as a nonspecific kind of biological process. However, there is evidence that this concept is probably fallacious.

A publication¹¹⁶ that compiles all substances tested for carcinogenic effects indicates that only about 17 percent of over 6000 substances show tumorigenic effects. Most of the substances were selected for testing because they were suspected of being carcinogenic, but the publication contains much overlap in terms of active constituents. Also, many studies cited are clearly inadequate for purposes of carcinogenicity testing, so it is difficult to evaluate what percentage of compounds tested actually have indicated tumorigenic effects.

In a study¹¹⁷ sponsored by the NCI from 1965 to 1968, approximately 140 pesticide and industrial chemicals were

tested for carcinogenic activity. Pesticides are known to possess high biological activity. In addition, the substances tested in the study were selected on the basis of a number of criteria, among which were: (1) published evidence of toxicity that suggested potential hazards to humans and (2) similarity between possible test substances and substances of known carcinogenic activity. Each substance was fed to both sexes of two strains of mice. A maximum tolerated dose (determined at a young age¹¹⁸) was administered orally for 18 months. Both positive and negative controls were used. Despite weighting in the selection of substances for testing, less than 10 percent produced tumorigenic effects.

The testing of chemicals at high dose levels is generally acknowledged¹¹⁹ to be necessary to overcome the statistical insensitivity of bioassays conducted with the limited numbers of animals that can be handled practically under laboratory conditions. Even with testing at maximum dosages, there are many negative findings from carcinogenic bioassays and such negative findings often are not published, many because they are rejected for publication.¹²⁰ For the A/D suspension, Saffiotti stated:

Not all chemicals can cause cancers, contrary to some ill-informed belief; in fact, only a relatively small proportion of the chemical species that have been studied are capable of such activity. The activity is dependent on a number of specific chemical and physical properties of the molecules, which are being gradually brought to light. It can be expected that, when thousands of new environmental chemicals will be tested, only a few hundred, or maybe just a dozen, will be found to be carcinogenic, and it will be possible to concentrate our preventive measures on those.¹²¹

Thus, the available evidence strongly indicates that all chemicals are not capable of causing cancer, but that only a small number of the total are.

3. Do Benign Tumors Characterize a Carcinogenic Response?

There are well-established morphological and histological criteria for distinguishing between benign and malignant tumors. Malignant tumors display characteristics of invasion of adjoining tissue or metastasis to other organs, or have the capacity to do so, whereas benign tumors lack this capacity.¹²² There is general agreement among scientific experts that the occurrence of tumors in animals in advanced stages of cancer--invasion and metastasis--must be taken as an unequivocal predictor of carcinogenic hazard to humans. Scientific opinion has varied, however, on the

issue of whether substances that induce benign tumors, and not malignant ones, should be regarded as posing a potential carcinogenic hazard to humans.

Historically, a distinction was drawn. For example, an FDA panel on carcinogenicity offered the following definition:

...a carcinogen is a substance that when administered by an appropriate route, causes an increased incidence of malignant tumors in experimental animals as compared with a control series of untreated animals.... The occurrence of benign tumors only would not classify an agent as a carcinogen.¹²³

and noted that:

The occurrence of metastases provides an unequivocal demonstration of malignancy. There are however, many tumors induced experimentally that are invasive and are classified as malignant, that metastasize only rarely during the average experiment. The absence of metastasis, in view of most pathologists, does not rule out the diagnosis of malignancy.¹²⁴

This position was supported in earlier reports, such as a report by an NRC committee:

The general term 'cancer' refers to the development of all kinds of malignant tumors. This term is not applied to non-malignant tumors.... It is recognized, however, that progression from benignancy to malignancy may occur.¹²⁵

The FDA panel did, however, note that:

...benign tumors may cause death in man and animals without ever undergoing malignant transformation. The induction of a benign tumor is, itself, therefore, an indication of a serious adverse reaction. There can be no doubt from a survey of experimental studies that benign neoplasms [tumors] are often precursors of malignancies...[and] it would be wise to take serious note of the occurrence of benign neoplasms in experimental studies....¹²⁶

However, considerations that benign tumors are hazardous without progressing to malignant stages and that benign tumors can be precursors to malignant tumors have led other expert committees to be more cautious in terms of assuring

that potential carcinogens are identified. For example, the carcinogenicity panel of the Mrak Commission stated:

...the majority of the Panel recognizes that benign tumors may become malignant. The Panel is unaware of any agents capable of inducing benign tumors only, which is to say, in the light of present knowledge, all tumorigens must be regarded as potential carcinogens. Thus, the majority of the Panel accepts tumorigenicity as an index of potential carcinogenicity.¹²⁷

Other reports as well support the position of considering the occurrence of benign tumors to be evidence of carcinogenicity. A joint FAO/WHO committee in 1961 stated:

In the assessment of the carcinogenic risk it is not considered relevant whether the tumor is benign or malignant since the conversion of the first to the second must be regarded as possible.¹²⁸

An ad hoc committee that reported to the U.S. Surgeon General in 1970 recommended that:

...The implication of potential carcinogenicity should be drawn both from tests resulting in the induction of benign tumors and those resulting in tumors which are more obviously malignant.¹²⁹

In the report of the ad hoc committee, the earlier definition of the FDA panel was specifically discussed, and the committee stated:

The assessment of the carcinogenic activity of a chemical depends on a variety of parameters. These include not only the total number of tumors induced but also their multiplicity, latent period, morphologic type, and degree of malignancy. The induction of tumors diagnosed as benign as a result of treatments has been interpreted by certain groups in the past as not sufficient to demonstrate a 'carcinogenic' effect. This is a dangerous position since few, if any, substances have produced only benign tumors and no malignant ones when properly and repeatedly tested.¹³⁰

The NCI Subcommittee on Environmental Carcinogenesis recently took a more moderate position:

The carcinogenicity of a substance is established when the administration to groups of animals in adequately designed and conducted experiments results in increases in the incidence of one or

more types of malignant neoplasms [tumors] (or a combination of benign and malignant neoplasms) in the treated groups as compared to control groups maintained under identical conditions but not given the test compound.... The occurrence of benign neoplasms raises the strong possibility that the agent in question is also carcinogenic since compounds that induce benign neoplasms frequently induce malignant neoplasms. [Emphasis added] In addition, benign neoplasms may be an early stage in a multi-step carcinogenic process and they may progress to malignant neoplasms; also, benign neoplasms may themselves jeopardize the health and life of the host.¹³¹

As will be discussed below, the work of the Subcommittee was conducted in the midst of the controversy over the use of cancer principles by EPA, and the caution expressed in the above definition is attributable in part to the controversy.

Since ultimately the concern is to avoid human cancer, it is instructive that a recent review of precancerous lesions in humans noted:

The progression of precancerous lesions to invasive cancer is an unpredictable process that cannot be prognosticated from morphologic appearance [reference omitted]. The time lapse between identification of precancerous lesions and the development of invasive cancer may be extremely variable, from a few months to many years, and it varies from organ to organ.... Virtually nothing is known about the biologic events that govern the capricious behavior of precancerous lesions.¹³²

The EPA principle that benign and malignant tumors characterize a carcinogenic response clearly reflects the consensus of expert opinion, yet this principle was among the most controversial.¹³³

4. Can "No-Effect" Levels Be Set for Chemical Carcinogens?

Toxic effects, and biological effects in general, are assumed, on the basis of much experience, to occur above a certain "threshold" or "no-effect" level of exposure to the causative agent. For many such effects, thresholds can be established for specific individuals as well as for defined populations at risk, even though thresholds for specific individuals may vary substantially within a population. The relationship between dose and response, and knowledge of the underlying biological stages leading to the effect in question, provide the basis for establishing such thresholds.

For many chemical carcinogens, a relationship between dose and response has been found to exist. Generally, the response increases as the dose increases, although in some cases, this relationship has been found either not to exist or to be opposite to that usually found (the carcinogenic response is greater at lower doses, possibly due to other toxic effects at higher doses).

The incidence of tumors and the period of latency often are related to dose. Because any individual has a finite lifetime, an individual threshold may exist because the latency may be so long that it exceeds the individual's lifetime. Also, in light of increasing evidence that cancer originates from a single cell, a threshold may exist for the particular affected cell; however, a large number of factors--age, sex, nutritional status, general state of health, etc.--can affect individual susceptibility, and there are many types of cells that can give rise to cancer. Thus, there is no means of predicting an individual threshold.

On the basis of general experience with other toxic effects, it is often argued that no-effect levels for a defined population can be set for chemical carcinogens by means of extrapolation from observed dose-response relationships. However, the variation in susceptibility to cancer among individuals makes it very difficult to place any confidence that an observed no-effect level in animals or in defined human populations (for which individual variations are small in comparison) is actually a threshold. In comparable animal test systems, chemical carcinogens can vary in the responses they elicit by as much as a factor of 10 million.¹³⁴

Furthermore, on the basis of what is known about the underlying biological events leading to cancer, the existence of thresholds for chemical carcinogens has been questioned by a WHO committee. Cited were:

- (1) the self-replicating nature of the cancer cell.
- (2) ...work...which has been interpreted to indicate summations of irreversible effects in carcinogenesis....
- (3) evidence from experiments on tumor initiation and promotion in skin carcinogenesis indicating lasting change induced by one tumor-initiating event.
- (4) the fact that cancer can occur in response to chemicals, even after single doses, long after their disappearance from the body.

(5) the possibility that cancer may result from mutation in a somatic cell [that is, a cell that contains all the necessary genetic materials to life, as opposed to a germ or reproductive cell which contains only half the necessary genetic material].¹³⁵

Many expert committees are in agreement that dose-response data cannot be used to set no-effect levels for exposure to chemical carcinogens. As early as 1959, an NRC committee stated:

...the possibility exists that doses at 'no-effect levels' [observed in experimental studies] do in fact exert carcinogenic effects but that the effects are too weak to detect with the numbers of animals feasible for routine testing. Such a possible effect, though extremely weak, might become evident in a large population potentially exposed to....[the substance]¹³⁶

The Committee also stated:

Information obtainable from dose-response curves prepared from data obtained in animal experiments appears of limited practical use in evaluating carcinogenic hazard for man. The apparent lack of quantitative correspondence in the carcinogenicity of a substance for different mammalian species and other complicating factors...make meaningful extrapolation from the 'no-effect' level of the dose-response curve to a 'safe-level' of use by man currently impossible....¹³⁷

The view that extrapolation from no-effect levels in dose-response studies to humans is currently impossible was reiterated¹³⁸ by a Joint FAO/WHO expert committee in 1961, a WHO expert committee in 1964, and in 1969 by a panel on carcinogenicity of the Mraz Commission.

An FDA panel discussed the quantitative methods available at that time for estimating a "virtually safe dose," particularly the methods proposed by Mantel and Bryan and by Druckrey,¹³⁹ and concluded:

Although it is possible in principle to estimate 'safe' levels of a carcinogen, uncertainties involved in downward extrapolation from test levels will usually result in permissible levels that are the practical equivalent of zero.¹⁴⁰

A report of an NRC committee presented what is considered to be a different view. With respect to the evaluation of carcinogenic hazards, the report stated

Although there are probably noncarcinogenic dosage levels for an experimental species in which a given compound is carcinogenic, there is as yet no generally accepted way of quantitatively extrapolating dose-response data in predicting a noncarcinogenic level for man. This fact is the principal basis for urging that such compounds be permitted for use in foods only if an explicit judgement has been made that demonstrable benefit greatly exceeds the risk.¹⁴¹

Despite this view, the committee introduced criteria for toxicologically insignificant levels of exposure that could be applied to natural or synthetic substances in the diet¹⁴² so that the substances might be considered safe without undergoing biological assay. In 1970, an NCI committee discounted the application of this concept to evaluations of carcinogenic risks:

The statement made in 1969...should be recognized as scientifically unacceptable.... No level of exposure to a chemical carcinogen should be considered toxicologically insignificant for man. For carcinogenic agents a 'safe level for man' cannot be established by application of our present knowledge. The concept of 'socially acceptable risk' represents a more realistic notion.¹⁴³

These illustrations should demonstrate that the cancer principles indeed have as a basis many national and international reports, although they are not unanimous on all points. However, two general groups of opponents to the principles within the scientific community can be discerned: those who oppose current carcinogenesis testing procedures (the concepts embodied in the principles) and those who ascribe to current practices in carcinogenic evaluations but oppose the language of the principles.

The former group tends to overemphasize the uncertainties in carcinogenesis evaluations and would apply a very high standard of proof to identify a carcinogen. This group also tends to place the burden of proof on the Agency--in contradiction to the requirements of FIFRA. The latter group, opposed to the language of the principles but not to the concepts embodied in them, tends to emphasize the distortions and gross oversimplifications in the principles. This group generally fears that the principles are so non-specific and simple that they could be used, in the extreme, as a checklist to regulate modifying factors such as the level of fat or protein in the diet, known to affect tumor formation in animals.

J. Organized Opposition

The Council for Agricultural Science and Technology (CAST) is a group composed of 17 trade and scientific associations.¹⁴⁴ CAST has issued several reports on the cancer principles.¹⁴⁵ In the report directly challenging the validity of the 9 principles used in the A/D suspension proceeding, CAST states:

This report was prepared by certain members of the scientific community who are not employed by either EPA or industry.

(A list of the members is provided in Appendix A). The report concludes:

The Environmental Protection Agency's nine 'principles' of carcinogenicity were developed as a policy basis for banning certain insecticides. Because most of these nine statements about carcinogenicity are unsound, they do not qualify as principles. Principles are fundamental truths, laws, or doctrines. The EPA principles are more appropriately called 'propositions,' which are expressions that may be believed, doubted, or denied.

It is correct that the cancer principles are not fundamental truths, laws, or doctrines. In that conclusion, however, are perhaps two of the more widely held, but erroneous, views on what the principles are and how they were intended to be used. First, EPA has not literally banned insecticides, but rather withdrawn registration of uses for which significant risks exist in light of the benefits of continued use and the adequacy of substitutes and has permitted other uses. In some cases, however, registration for most uses of a pesticide have been withdrawn.

Second, the term "principles" has been used in this connection for over 25 years. In part, the confusion stems from equating the principles to "facts" for official notice. But facts in this legal context differ from "facts" in the scientific sense. Since EPA sought "official notice of certain facts" in the H/C and Mirex proceedings, the principles were given more credence than was actually intended. The principles were not presented as irrefutable facts or laws of nature, but rather as the most widely used and scientifically acceptable means of evaluating carcinogens in the environment.

CAST attacked the use of the principles (as did the industrial registrants and USDA in each proceeding) in essence to discount the risks. However, the proceedings for

cancellation, suspension, or fact-finding under FIFRA require a weighing of risks and benefits associated with pesticide use. As summary points of the criteria or framework for evaluating the carcinogenicity of a substance, the principles do not obviate the need to judge the validity and strength of the actual experimental studies, which are the core of the analysis of risks; nor do the principles pre-empt the balancing of risks and benefits.

CAST also highlighted much of the scientific uncertainty associated with the evaluation of carcinogenesis. The comments illustrate some of the differences between the arguments adduced by EPA in support of the principles and those adduced by the registrants in the H/C and Mirex proceedings.

One such difference concerns whether the burden of proof should rest with the Agency or with the registrant. In a letter to CAST, the EPA Deputy Assistant Administrator for Health and Ecological Effects wrote:

I am particularly disturbed by certain suggestions in the task force report that the pesticides suspended or cancelled by EPA have not been 'proved' to cause cancer in man. This places the burden of proving safety on the public, rather than placing the burden of proving safety on the industry involved, as required by law.¹⁴⁶

This difference in where the burden of proof is placed is illustrated in the discussion of principle number 8 in the CAST report. Principle number 8 (see Table 2) is:

A carcinogenic agent may be identified through analysis of tumor induction results with laboratory animals exposed to the agent, or on a post hoc basis by properly conducted epidemiological studies.

The CAST report states:

Carcinogenesis data from experiments on laboratory animals of course lead one to infer that similar effects may be observed with other animal species and with humans. One must recognize, however, that the rodents used experimentally may be too sensitive for predicting chemical carcinogenesis effects in humans. The rodents are certainly too sensitive to tumor-producing viruses to be predictive. The monkey is much more like humans.

The differences involve value judgments. First, the use of animals, which individually may be more sensitive than humans to carcinogenic agents, allows the use of test groups

that are smaller in number than the human population that might be exposed. In using rodents, greater value is placed on the possibility of mistakenly preventing a "safe" substance from being used than on the possibility of allowing distribution of a harmful one.

In recommending the monkey for such tests, CAST emphasizes a greater similarity between man and monkeys, but ignores the practical problems of using monkeys and the advantages of using rodents. Monkeys are very expensive, and many species are not readily available. For population studies, the cost of maintenance and support is prohibitive. Also, experiments with monkeys require many more years to produce results than do similar experiments with rodents.

The use of monkeys for routine testing was discussed in the report of an FDA panel:

There is general recognition that new species in addition to the commonly used rodents are needed for carcinogenicity testing. Increasing the number of species used would greatly increase the margin of confidence with which safety can be predicted.... The most discussed additional species are primates. Recent studies show certain primates to be highly susceptible to some carcinogens; however, much more work is needed to justify the additional expense and time that would be necessitated by the introduction of these animals in routine test procedures.¹⁴⁷

The panel was concerned that a carcinogenic agent might not be detected, such as beta-naphthylamine which is known to induce cancer in humans, monkeys, dogs, and hamsters, but failed to induce cancer in mice, rats, guinea pigs, and rabbits.

The CAST report also emphasizes the importance of epidemiological studies using medical records for occupationally exposed individuals compared to the general population. The problems with reliance on epidemiological studies for identifying carcinogens have been discussed and, of course, if relied upon, place an immense burden on the Agency to demonstrate harm. CAST ignores these problems as well as the requirement in FIFRA and the explicit statement by the courts that the burden of establishing safety rests at all times with the registrant.

The principles were intended as summary points based on extensive documentation in the record. Without this documentation, the principles are naive and oversimplified and are greatly in need of qualification. An example of how the CAST report qualified the principles is as follows:

EPA principle -- Any substance which produces tumors in animals must be considered a carcinogenic hazard to man if the results were achieved according to the established parameters of a valid carcinogenesis test.

CAST rewording -- Any substance which has been shown to produce cancers in laboratory animals must be suspected as presenting a potential cancer hazard to humans. For substances on which critical information is required, adequate definitive carcinogenesis studies using at least two species of laboratory animals (which are normally rodents) should be conducted. If positive evidence of carcinogenicity is obtained, tests on nonrodents, preferably monkeys, should be carried out (except for the expense, it would be preferable to use monkeys at the outset). The results of these experiments should be used in conjunction with all relevant information available from occupational medicine and other epidemiological evaluations on humans as a basis for establishing finite allowable exposure limits for humans.

Differences between the views expressed by CAST and the many expert committees concerning the burden of proof can be highlighted by comparing this statement with one from the 1970 report to the Surgeon General:

Evidence of negative results, under the conditions of the test used, should be considered superceded by positive findings in other tests. Evidence of positive results should remain definitive unless and until new evidence conclusively proves that the prior results were not causally related to the exposure.¹⁴⁸

CAST applies a high standard of proof to establish the causal link between the substance and cancer. The 1970 report applies a high standard of proof to dispel the suspicion of carcinogenicity.

Another point of confusion about the principles can be illustrated by considering a meeting organized by the Synthetic Organic Chemical Manufacturers Association (SOCMA) on chemicals and cancer.¹⁴⁹ The program for the SOCMA meeting included a discussion of EPA's regulatory actions in which the cancer principles were used and also actions involving decisions on carcinogens by other agencies. The CAST report was summarized at the meeting, and discussion turned to the Toxic Substances Control Act.¹⁵⁰

The principles were cited as the potential basis for implementing the Act. The principles, it was suggested,

would serve as a checklist for decisions on whether to ban a substance. Therefore, the principles would, in effect, extend to industrial chemicals in the environment the approach of the so-called Delaney Clause in the Federal Food, Drug, and Cosmetic Act,¹⁵¹ which prohibits any amount of a carcinogen from being used as a food additive.

There are several problems with this view. The principles were not intended to be a checklist and were not used in that way. Because they set the framework for the analysis of the risk of cancer, they do not eliminate a step in which the experimental studies are reviewed and evaluated. Also, their use does not eliminate the stage at which risks and benefits are balanced in reaching a final decision as to appropriate control measures.

In the Toxic Substances Control Act, there are levels of authority that can be exercised before manufacture and sale of a substance is severely restricted. Furthermore, the Act requires, as does FIFRA, that the use of a substance be considered in a decision of whether and how to regulate, not just the toxicity, which might be the carcinogenicity of the substance. Thus, the use determines the exposure patterns, which along with the toxic properties of the substance, form the basis for an evaluation of the risk posed to humans and the environment.

Generally, organized efforts to oppose the principles emphasize the uncertainties involved in regulating carcinogens, but fail in any forceful way to undermine the validity of the concepts and judgments upon which they are based. The weight of scientific advice rests with the principles, and is consistent with the placement of the legal burden of proof on industry for pesticide registration decisions.

K. Attempt at Peer Review

Shortly after EPA sought official notice of the 17 cancer principles in the H/C cancellation proceeding, William M. Upholt, the Senior Science Advisor at EPA to the Assistant Administrator for Water and Hazardous Materials, wrote to NCI about the 9 cancer principles:

The opinion I would like from you is whether or not these nine points as stated are scientifically sound, regardless of the testimony upon which they were based. If these principles are scientifically sound...we will doubtless use them in other regulatory actions.... On the other hand, we would not want to perpetuate them in other types of action if they are unsound or misleading.¹⁵²

He stated that he had reviewed a portion of Saffiotti's testimony and added:

...I see no reason to question whether or not it reflects the official position of the National Cancer Institute...we are more concerned about the conclusions that were drawn from the record as a whole.

In a reply to EPA, NCI stated:

The obvious importance of rigorously reviewing and critiquing these principles prompts me to suggest that the National Cancer Advisory Board's Subcommittee on Environmental Carcinogenesis be involved in this effort.¹⁵³

According to the NCI official who replied to EPA, a number of different advisory or coordinating committees were considered before choosing the Subcommittee on Environmental Carcinogenesis. The groups considered were narrowed to three: 1) the Interagency Collaborative Group on Environmental Carcinogenesis, 2) the HEW Committee to Coordinate Toxicology and Related Programs, and 3) the Subcommittee on Environmental Carcinogenesis. The first was rejected because its function was primarily for coordination, and therefore, not appropriate. The second was rejected because as a committee of government officials it would be difficult to place non-government scientists on its roster. The Subcommittee on Environmental Carcinogenesis had debated a number of problems associated with the chemical carcinogenesis program at NCI. Because a number of its standing members were not research scientists in the field of cancer, the Subcommittee did much of its work through consultants. (A list of members and consultants is provided in Appendix B.)

Upholt later withdrew his request for review by NCI since recent developments in the H/C cancellation proceeding "...have raised the possibility that these nine points, or a similar set, will be submitted to the National Academy of Sciences for evaluation...." He added:

Please understand that this does not reflect any reservations on the desirability of a review.... But as long as this litigation is pending, I would not want to ask for such review even though my interest was in the application of the principles to non-pesticide problems.¹⁵⁴

The Subcommittee met and discussed the 9 principles from A/D (see Table 2) and Saffiotti's "draft for discussion" (see Table 4). Upholt and Saffiotti explained the history of the principles and how the issue came to the

Subcommittee. The discussion was far-ranging. At one point Upholt said:

...he was concerned that the use of these principles for regulatory and legal purposes could result in their being set in concrete when, in fact, the scientific community may or may not be prepared to embrace and endorse such principles.¹⁵⁵

Saffiotti said that since the principles were derived in large part from his testimony in the A/D suspension proceeding, he was in a sense responsible for them, but added:

...that he was not responsible per se for those nine principles nor was he given an opportunity to review them prior to their becoming public information....

He said he had agreed to:

...send a draft to Mr. Howard attempting to rectify any damage done by the original nine principles.

He pointed out that his draft conveyed his own personal views. The Chairman of the Subcommittee then stated the desire of the Director of NCI that "...the Subcommittee, with whatever additional consultants that might be necessary...address the principles..." and include the draft by Saffiotti.

Subsequent to the meeting, the NCI Director wrote to the Chairman and asked the Subcommittee "...to determine whether the current state of the art will permit the development of definitive and interpretive guidelines..." that "...better define, in functional terms, a chemical carcinogen..." and which "...can be used for interpreting carcinogenicity data."¹⁵⁶ A similar letter was sent to EPA.¹⁵⁷

Howard, an EPA attorney in OGC, replied for the Administrator. The letter contains a regulatory history of pertinent EPA decisions, which is very similar to the passages in the pesticide regulations¹⁵⁸ and describes the basis for the principles. Although one of the underlying documents is cited in the letter, the citations are predominantly from the Federal Register, an unfortunate way to address the Director of NCI on cancer issues.

At the second meeting of the Subcommittee, the following motion was passed:

MOVED that the draft by Dr. Umberto Saffiotti titled 'Statement in Principles of Chemical Carcinogenesis in Relation to the Evaluation of

Carcinogenic Hazards' dated 8/25/75 be considered a highly useful background for discussions on the definition of a carcinogen. This committee does not feel, however, that this paper provides an adequate definition of a carcinogen for use by regulatory agencies or for legislative purposes. In response to Dr. Rauscher's request, therefore, this committee should consider de novo the problem of deriving a definition of a carcinogen suitable for the latter purposes. A subcommittee of this committee, recruiting additional expertise if necessary, be approved to consider this difficult and complex task.¹⁵⁹

This motion was widely misinterpreted. The cancer principles were rejected by the Subcommittee, but chiefly on the basis of their format--or more accurately, the way in which they might have been used--rather than their substance.

The Subcommittee's motion was introduced into both the H/C and Mirex proceedings along with a first working draft generated by the Subcommittee the day following the second meeting. In the Mirex proceeding, Allied sent a letter¹⁶⁰ to the ALJ, which cited a trade publication and a report by the Subcommittee Chairman to the National Cancer Advisory Board,¹⁶¹ in which a portion of the motion was quoted as reported to the Advisory Board. The portion stated that the principles were useful background, but that the Subcommittee did not consider it an adequate definition of a carcinogen for use by regulatory agencies and would consider de novo the problem of deriving a definition. However, the trade publication stated:

The subcmte. [sic] voted to reject 17 principles proposed by Umberto Saffiotti, NCI carcinogenesis associate director, as the basis for establishing criteria. Saffiotti's principles have been bandied about widely as NCI policy and have been pivotal in pending Environmental Protection Agency actions on pesticides. The cmte. [sic] decided that although the Saffiotti document is a great backgrounder, it did not meet the request of NCI Director Frank Rauscher for clear standards on defining hazards.¹⁶²

EPA sought to correct the misunderstanding on the motion by the Subcommittee. EPA's reply to Allied's contention that the 17 principles were rejected states:

Even a cursory reading of the transcript of that meeting and the working draft produced by that meeting shows that the subcommittee did not reject the scientific facts sought to be officially

noticed as a sound basis for evaluating carcinogenicity...the subcommittee meeting provides still further support for the widely accepted view that laboratory animals should be used to evaluate potential human carcinogens, that there is no sound basis presently available for establishing a safe level of human exposure to carcinogens and that the induction of benign and malignant tumors are indicative of a carcinogenic response.¹⁶³

Later, both the Chairman and Executive Secretary of the Subcommittee sent communications¹⁶⁴ to EPA to straighten out the misunderstanding about the draft and its relation to the principles. In his telegram, the Chairman states:

We hope that this draft will not be misinterpreted or used prior to its completion. It should be reiterated that this subcommittee report is responsive to a request of the Director of the NCI and advisory to him.

At the next meeting of SEC the Chairman said:

It is unfortunate that our deliberations have resulted in the arousing of considerable emotion and have possibly been misused; for certain our procedures have been misunderstood....¹⁶⁵

He referred in particular to a charge made in public at a meeting of the Environmental Study Conference of the U.S. House of Representatives. The charge was made that the Chairman had released the draft without the approval of the Subcommittee members and that the draft had influenced the ALJ in his recommended decision on H/C.¹⁶⁶ The ALJ has acknowledged that the draft did, in fact, influence his decision. However, the draft was released in compliance with the Freedom of Information Act and the Federal Advisory Committee Act.¹⁶⁷

At the next meeting of the Subcommittee, the draft was completed and subsequently approved by the National Cancer Advisory Board. The introduction to the report contains the following:

The complexity of the problem dictates that the evaluation of the potential human hazards of a given agent must be individualized in terms of the chemical and metabolic aspects of that agent, its intended use(s), the data available at the time that the decision must be made, and other factors pertinent to the case under consideration. Each case must be considered on its own and the criteria appropriate for one agent may not necessarily apply to another.¹⁶⁸

As in some of the criticism of the cancer principles, the complexity and uncertainty of evaluating carcinogenic risk is emphasized, but the adoption of a single set of criteria is rejected.

Despite this, there is little in the report that counters the concepts embodied in the principles. On the question of the use of studies in experimental animals (cited in the introduction to this case study), the report does not differ substantially from the principles.

On the issue of whether to characterize the occurrence of benign tumors as a carcinogenic hazard the report states that the determination of whether a tumor is benign or malignant is recognized to depend on the tissue in which the tumor occurs and should:

...follow standard criteria used by experimental oncologists and pathologists.... In equivocal cases, the diagnosis of a specific lesion may require a panel of experts, recognizing that they may not always agree.¹⁶⁹

The document differs in the treatment of the question of benign tumors under criteria for human studies and under criteria for animal studies. For human studies, the induction of exclusively benign tumors by a substance means that it should be considered a possible carcinogen. However, if exclusively benign tumors are found in animal studies, it raises the strong possibility that the substance is carcinogenic, but it should be further evaluated.

To clarify the situation in which benign and malignant tumors are both present in an animal study, the report states:

In experiments where the increased incidence of malignant neoplasms [tumors] in the treated group is of questionable significance, a parallel increase in incidence of benign tumors in the same tissue adds weight to the evidence for carcinogenicity of the test substance.¹⁷⁰

This is particularly important because some studies, especially one by FDA cited in the A/D case, counted only malignant tumors and not the benign tumors also present.

The difference between the Subcommittee criteria and the cancer principles on the question of benign tumors removes the possibility of misinterpretation in a "worst case" situation, which has rarely, if ever, been observed. In that situation, a study, properly designed and conducted, of laboratory animals exposed to a substance would lead to the occurrence of only benign tumors of a type not found to

transform to malignant tumors. The Subcommittee criteria suggest that, in this situation, further study is needed to clarify the suspicion of carcinogenicity of the substance, and no conclusion can be drawn about its carcinogenicity without further study. The cancer principles would lead to the interpretation of that situation as sufficient to characterize the agent as potentially carcinogenic to humans.

The report avoids the question of a "no-effect" level by emphasizing the uncertainties involved:

Quantitative extrapolation from animal studies for the purposes of evaluating human risks entails large uncertainties at the present time. Each case must be individually evaluated, taking into consideration such factors as adequacy of experimental design, significance of the data, dose-response relations, duration of exposure, route of administration, metabolism (including species variations), host susceptibility, co-factors, and other modifying factors and the amount of material to which humans would be exposed.¹⁷¹

In a final section, the evaluation of benefits versus risks is treated:

In those cases in which a compound has been proved to be carcinogenic there remains the decision to what extent the possible risks to man are counterbalanced by the possible social, economic, or medical benefits of that substance. Scientists should play a role in those decisions by providing and interpreting the available data. The final decision, however, must be made by society at large through informed governmental regulatory and legislative groups.¹⁷²

This part of the report highlights the stage in the decision-making process to which the cancer principles apply and for which a direct role for scientists as experts is desirable. That role is to evaluate the strength and appropriateness of data on the carcinogenicity of an agent, an evaluation upon which the assessment of the risk of cancer to humans is critically dependent.

When compared to the cancer principles, the Subcommittee criteria make explicit more factors to be considered in an evaluation of risk. Among these are: the experimental design, the relationship of dose to response in the animals, the duration of exposure, the route of administration of the agent to the animals, metabolic pathways, and a number of other modifying factors. As a more sophisticated statement of the complexity inherent in evaluations of

carcinogenicity, the Subcommittee document provides more flexibility to decision makers in specific cases than the principles.

In summary, the differences between the cancer principles, particularly those revised by Saffiotti, and the Subcommittee criteria are chiefly (1) in the format of presentation, (2) in the interpretation of whether the occurrence of exclusively benign tumors appropriately characterize a carcinogenic effect in laboratory animals, and (3) a discussion of in vitro tests (not mentioned in the principles).

Perhaps the most cogent statement by a scientist on the cancer principles is one by Russell W. Peterson, former Chairman of the Council on Environmental Quality.

The various cancer principles seem to have caused far more controversy so far than any regulation aimed at a specific chemical. I am not wedded to any of the proposals, but I cannot help feeling that much of the criticism directed toward them arises either out of vested interest, or simple misinformation.... Though scientists have a particular training and expertise which uniquely qualify them to evaluate scientific questions, they possess no special status with respect to social value judgments. And it is the value judgments implicit in the cancer principles, not the medical or scientific aspects, which are stimulating most of the controversy.¹⁷³

Peterson discussed several principles and emphasized those with clear scientific underpinnings. On the question of how to evaluate benign tumors, however, Peterson acknowledged the social value judgment inherent in the decision that "...because certain induced tumors transform into malignancies; and because we can seldom predict which tumors will become malignant and which will not, we should regard all tumorigens as possible carcinogens."¹⁷⁴

Peterson also discussed the extrapolation of animal data to an estimation of human risk, noting that there is no proven link between cancer effects in humans and in animals. He added:

It is in these public policy areas that the various sets of proposed cancer principles have been attacked as unscientific--and that, of course, is absolutely correct. They are unscientific because they are not scientific matters. They are value-judgments made on behalf of the public under legislative statutes. They are not always wise, and they do not always prove to be right, because

they are formulated on the basis of insufficient knowledge. Yet such judgments--which do not fall into the domain of scientists any more than they do of any other citizen--must be made.¹⁷⁵

To account for the considerable controversy surrounding the use of the principles, it is necessary to keep in mind the various value orientations of the participants.

Explicit cancer policy expressed in a set of summary statements has been abandoned by EPA and new procedures have been adopted for handling assessments of the human risk of cancer from pesticides and other environmental pollutants. The new procedures have quelled the controversy by allowing EPA to rely on implicit criteria and policies. At this point, however, it appears that the application of implicit criteria to the evaluation of carcinogenicity is not likely to be very different than the explicit criteria in the principles.

IV. CONCLUSIONS

A. Nature of Controversy

The political clash between industrial and environmental interests was fueled by debate in the scientific and medical communities. The debate, particularly among those with agricultural interests, was marked by confusion over what the principles actually were and how they were used. Many critics of the principles failed to acknowledge the fact that the principles were supported in many reports issued by expert committees.

Because cancer is so poorly understood, the information base for regulatory actions to prevent exposure to potential carcinogens is plagued with uncertainties. Yet, because of the uncertainties and complex issues involved, the consensus among committees on the framework for the evaluation of carcinogenicity is impressive.

However, a number of scientists, particularly toxicologists, disagree with the concepts embodied in the principles, and therefore with the judgments of the expert committees from which they were derived. The disagreements often are predicated upon different value orientations or different views about who should bear the burden of proof. As mentioned, some hold the view that substances found to be carcinogenic in animals ought to be tested in humans. Others believe that only clearly malignant tumors should characterize a carcinogenic response or that all chemicals are capable of causing cancer in rodents. Many feel that all toxic effects have threshold levels of action, and that cancer is no exception. A number of scientists also believe

that in general the benefits associated with the various pesticides justify the risks. Finally, many believe that the Government--and ultimately the public--should bear the burden of proof for demonstrating harm rather than industrial registrants bearing the burden of proof for demonstrating safety. The latter view not only contradicts the views of cancer experts expressed over the past 25 years, but is not in keeping with the statutory framework set by Congress for regulating pesticides.

Perhaps the most widespread confusion was over the use of the principles. An increasing number of animal bioassays, particularly by NCI, were resulting in positive findings of carcinogenicity. This prompted the fear that a large number of regulatory actions would be taken that neither weighed the risks against benefits, nor considered the hazards of substitutes that might pose greater risk; that is, the principles would be used as a checklist to ban substances. This ignores the actual role that the principles played in risk/benefit determinations.

As criteria for evaluating carcinogenicity data, the principles provide only a framework for estimating the level of risk. They were not designed to be used by themselves to estimate the level of risk associated with specific uses of a pesticide. An estimation of the level of risk must be based on the strength of the evidence gathered on a specific pesticide and entails an evaluation of the experimental data on effects in animals (including the number of species and strains, route of administration of the test substance, degree of malignancy observed, etc.), the data on effects in humans and on the environment, and an examination of possible routes of human exposure and the fate of the substance in the environment. The level of risk, and not simply the fact of risk, enters into the final determination of whether the risks are justified by the benefits.

Furthermore, neither the Toxic Substances Control Act nor FIFRA requires EPA to ban cancer-causing chemicals. The DDT, A/D, and H/C decisions all permitted some uses of the pesticides--for example, public health and pest quarantine uses of DDT, use of A/D and H/C for termite control and other uses. Thus, risk/benefit determinations have not been made solely and rashly on the basis of risk. In fact, the decisions concerning DDT, A/D and H/C were certainly not characterized by rashness. Many years elapsed between the time that studies indicating various hazards, including cancer, were completed and cancellation proceedings initiated.

One additional political factor that contributed to the controversy over the use of cancer principles is the tension that existed between the Agency's scientists, particularly in OPP but also in other offices, and the lawyers in OGC.

Without recognition of the scientific support for the principles, one might conclude that the Agency's lawyers were developing cancer policy. The views of the scientists and expert committees relied upon by OGC certainly differed in many respects from those of many Agency scientists, but the apparent scientists/lawyers split in EPA can be explained in part by the advocacy of the lawyers for regulatory action to protect the public and the caution of the scientists in expressing the need for a sound scientific basis for regulatory action.

Also, in one respect, lawyers and scientists tend to approach the problem of cancer principles in different ways. This is best illustrated by the legal use of the term "facts" and the scientific sense of the term. In the legal sense of the term, the Agency's cancer principles are facts, but not in the scientific sense. Thus, the lawyer/scientist split is both a reflection of the struggle between activist and non-activist elements in EPA and a reflection of two cultures, one scientific and the other legal.

B. How the Controversy Might Have Been Averted

Given the uncertainties inherent in evaluations of carcinogenicity and the lack of unanimity within the scientific community on the concepts embodied in the principles, the controversy over the use of cancer principles seems inevitable. However, more explicit reference to the underlying evidence for and the policy presumptions upon which the principles were based would likely have averted some of the misunderstanding about their validity. A discussion of how they were used in conjunction with the evaluation of the carcinogenic risk of the pesticides would probably have avoided some confusion over their use and focused the debate on whether the risk/benefit determinations could be improved.

A discussion of policy presumptions inherent in the principles might have allowed a debate on the value judgments of the participants to occur. An explicit debate on values would have been more to the point than the debate over the validity and use of the principles. The controversy might also have been largely defused if the cancer principles or some similar document containing criteria for evaluating carcinogenicity were nationally adopted by the Department of Health, Education, and Welfare or perhaps by the President through a special commission.

Regulatory efforts to control pesticides, food additives, drugs, industrial chemicals, consumer products, and other substances that show evidence of carcinogenicity place an immense burden on the scientific resources of the United States. Some kind of centralization of analysis is

worth considering. However, there can be no national policy in the sense that policy implies a risk/benefit determination. Different agencies with different missions will make different risk/benefit determinations. For example, the benefits of a carcinogenic drug may clearly outweigh the risks, whereas the risk of occupational exposure to the substance may not be justified in light of feasible control technology to reduce or eliminate the exposure.

What might be possible is the national adoption of common criteria for risk assessment that will permit industry, Government, and others to anticipate the kinds of data that will be used in making risk determinations. To the extent possible, recommended methods of estimating the level of risks involved could be included. Nationally adopted criteria for carcinogenicity evaluations may also help to alleviate the need for extensive reinterpretations of the data as in the cases of A/D and H/C, since much of the difference in interpretations seems to be due to different criteria. Something like EPA's cancer principles are used either explicitly or implicitly in all regulatory decisions in which cancer is a factor. A consistent approach to identifying carcinogens and evaluating the risk posed to humans is needed.

NOTES

- 1 There are a number of people who were particularly helpful to me during the course of this case study, all of whom I wish to thank and some of whom I wish to acknowledge. This study benefited considerably as a result of Larry McCray's interest and attention to the issues involved in formulating cancer policy. Much of the insight into the presumptions inherent in the principles can be traced to discussions with Larry. The other members of the staff of the Committee on Environmental Decision Making--Rick Lowerre, Raph Kasper and Bob Burt--also were very helpful to me in coming to an understanding of the underlying issues involved in the use of explicit cancer principles.

Many of the individuals directly involved in the debate over cancer principles were especially candid and willing to share their experiences. At EPA, Bill Upholt, Lawrence Plumlee, Elizabeth Anderson, John Bonine, and Glenn Schweitzer deserve special thanks. Former EPA employees who gave willingly and often of their time are John Kolojeski, Jay Turim, Jeff Howard, Frank Sizemore, and Bill Reukauf. At the National Cancer Institute invaluable assistance was provided by Gary Flamm, Herman Kraybill, Umberto Saffiotti, Marv Schneiderman, and Gio Gori. Joe Sloan and Walt Appleby of Shell Chemical Company were exceptionally helpful in several discussions, but especially in providing notes and comments on a draft on this study. Ian Nisbet was also helpful.

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- 2 No effort was made to interview each of the participants or to have them review this study. Any errors of fact or interpretation are solely the responsibility of the author.

- 3 A considerable amount of the material in this section is based on material in the preamble to a draft regulation of the Occupational Safety and Health Administration (OSHA) in the Department of Labor, "Identification, Classification, and Regulation of Toxic Materials Posing a Potential Occupational Cancer Risk to Workers." I was a consultant to Clement Associates, Inc., the firm with which OSHA contracted to draft the regulation.
- 4 D.L. Levin, S.S. Deresa, J.D. Goodwin, II, D.T. Silverman, Cancer Rates and Risks, DHEW Publ. No. (NIH) 76-691, (Washington, D.C.: Government Printing Office, 2nd Edition, 1974), pp. 1-3; President's Council on Environmental Quality (1975), "Carcinogens in the Environment," In: Environmental Quality - The Sixth Annual Report of the Council on Environmental Quality (Washington, D.C.: Government Printing Office); J.H. Weisburger, "Chemical Carcinogenesis," In L.J. Casarett and J. Doull, eds., Toxicology: The Basic Science of Poisons (New York: Macmillan, 1975), pp. 333-378; J. Cairns, "The Cancer Problem," Scientific American, November 1975, pp. 64-72.
- 5 L.J. Old, "Cancer Immunology," Scientific American, May 1977, pp. 62-77; S.K. Carter, "Immunotherapy of Cancer in Man," American Scientist, Vol. 64 (1976), pp. 418-423.
- 6 P.J. Fiaklow, "The Origin and Development of Human Tumors Studied with Cell Markers," New England J. Medicine, Vol. 219 (1974), pp. 26-35; S.M. Gartler, "Utilization of Mosaic Systems in the Study of the Origin and Progression of Tumors," In: J. German, ed., Chromosomes and Cancer, (New York: Wiley/Interscience, 1974), pp. 313-334.
- 7 Weisburger, supra note 4, p. 333ff.
- 8 Council on Environmental Quality (1975), supra note 4, p. 27; P. Cole and M.B. Goldman, "Occupation," In: J.F. Fraumeni, Jr., ed., Persons at High Risk of Cancer (New York: Academic Press, Inc., 1975), Table 1, pp. 172-176.
- 9 Weisburger, supra note 4, pp. 334-336.
- 10 Council on Environmental Quality (1975), supra note 4, p. 12.
- 11 U.S. General Accounting Office (1976) Report to Congress, "Federal Efforts to Protect the Public from Cancer-Causing Chemicals Are Not Very Effective," Publication No. B-164031(2), MWD-76-59. (Washington, D.C.: U.S. General Accounting Office), p. 1.

- 12 S.S. Epstein, "The Political and Economic Basis of Cancer," Technology Review (July/August 1976), pp. 35-43.
- 13 Levin, supra note 4, Figure 7, p. 14.
- 14 World Health Organization (1964) Prevention of Cancer, Technical Report Series, No. 276 (Geneva: World Health Organization); E. Boyland, "The Correlation of Experimental Carcinogenesis and Cancer in Man," Progress in Experimental Tumor Research, Vol. 11 (1964), pp. 22-34; S.S. Epstein, "Environmental Determinants of Human Cancer," Cancer Research, Vol. 34 (1974), pp. 2425-35; L.J. Vunham and J.C. Bailar, III, "World Maps of Cancer Mortality Rates and Frequency Ratios," J. National Cancer Institute, Vol. 41, No. 1 (1968), pp. 155-163.
- 15 E.C. Hammond, "Tobacco," In: Fraumeni, ed., supra note 8, pp. 131-138.
- 16 K.J. Rothman, "Alcohol," Ibid., pp. 139-150.
- 17 J.W. Berg, "Diet," Ibid., pp. 201-229.
- 18 S. Jablon, "Radiation," Ibid., pp. 151-166.
- 19 U.S. General Accounting Office (1976), supra note 11, p. 133.
- 20 Cole and Goldman, supra note 8, pp. 167-184.
- 21 J.A. Miller, "Naturally Occurring Substances That Can Induce Tumors," In: National Research Council (1973) Committee on Food Protection, Toxicants Occurring Naturally in Foods, 2nd Edition (Washington, D.C.: National Academy of Sciences), pp. 517-520.
- 22 I.B. Weinstein, N. Yamaguchi, R. Gebert, and M.E. Kaighn, "Use of Epithelial Cell Cultures for Studies on the Mechanism of Transformation by Chemical Carcinogens," In Vitro, Vol. 11, No. 3 (1975), pp. 130-141.
- 23 R.W. Miller, "Host Factors," in Fraumeni, ed., supra note 8, pp. 121-128.
- 24 S.S. Epstein, supra note 12, p. 35; L.S. Greenberg and J.E. Randal, "Waging the Wrong War on Cancer," The Washington Post, Outlook, May 1, 1977, p. C1; W.R. Muir, "Federal Regulation and Prevention of Cancer," Ecology Law Quarterly, to be published, supra note 1; as a further illustration of the political nature of efforts to identify and prevent exposure to potential carcinogens, one example is worth mention. On April 14,

1976, Umberto Saffiotti announced his intention to resign as the Associate Director for Carcinogenesis in the Division of Cancer Cause and Prevention at the National Cancer Institute and accept the position of Chief of the Experimental Pathology Branch within the Carcinogenesis Program. His letter of resignation outlined his frustrations in running the carcinogenesis program and provides an interesting glimpse of many of the issues involved. Memorandum from Associate Director, Carcinogenesis Program, DCCP, NCI, to the Director of NCI and the Director of DCCP, Staff, Advisors, and Collaborative Participants in the Carcinogenesis Program, April 23, 1976, published in the Congressional Record, April 29, 1976, pp. S6255-6256.

- 25 U.S. General Accounting Office, supra note 11.
- 26 Rothman, supra note 16.
- 27 I.J. Selikoff and E.C. Hammond, "Multiple Risk Factors in Environmental Cancer," In: Fraumeni, ed., supra note 8, pp. 467-483.
- 28 Cole and Goldman, Ibid., p. 177.
- 29 Ibid., p. 168.
- 30 R.M. Miller, supra note 23.
- 31 National Cancer Advisory Board, Subcommittee on Environmental Carcinogenesis, "General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances: Report of the Subcommittee on Environmental Carcinogenesis, National Cancer Advisory Board," J. National Cancer Institute, Vol. 58, No. 2 (1977), p. 461.
- 32 World Health Organization (1961) Fifth Report of a Joint FAO/WHO Expert Committee on Food Additives, Evaluation of the Carcinogenic Hazards of Food Additives, Technical Report Series No. 220 (Geneva: World Health Organization), p. 6.
- 33 V. Riley, "Mouse Mammary Tumors: Alteration of Incidence as Apparent Function of Stress," Science, Vol. 189 (August 8, 1975), p. 465-467.
- 34 National Research Council (1975) Environmental Studies Board, Pest Control: An Assessment of Present and Alternative Technologies, Vol. 1, "Contemporary Pest Control Practices and Prospects: The Report of the Executive Committee," (Washington, D.C.: National Academy of Sciences), Table 4, "Results of Rodent Tests on Substances Known to be Carcinogenic to Man," pp. 67-

73, and Table 5, "Degree of Exposure and Reported Cancer Frequencies for Agents Carcinogenic to Man and Laboratory Animals," pp. 75-78.

- 35 J.M. Sontag, N.P. Page, U. Saffiotti (1976) Guidelines for Carcinogen Bioassay in Small Rodents, National Cancer Institute Carcinogenesis Technical Report Series No. 1, Publication No. NCI-CG-TR-1, (Washington, D.C.: U.S. Government Printing Office).
- 36 I. Berenblum, Ed., A Report of the Panel on Carcinogenicity of the Cancer Research Commission, UICC, Carcinogenicity Testing (Geneva: International Union Against Cancer, 1969), p. 18.
- 37 The following list is intended to be broadly representative, and not to be exhaustive:
 - National Research Council (1959) Food Protection Committee, Problems in the Evaluation of Carcinogenic Hazard from Use of Food Additives, Publication No. 749 (Washington, D.C.: National Academy of Sciences).
 - World Health Organization (1961), supra note 32.
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 - U.S. Department of Health, Education, and Welfare (1970) Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens, Report to the Surgeon General, U.S. Public Health Service Evaluation of Environmental Carcinogens, (Washington D.C.: National Institutes of Health, U.S. Department of Health, Education, and Welfare).
 - National Research Council (1970) Food Protection Committee, Evaluating the Safety of Food Chemicals (Washington, D.C.: National Academy of Sciences).
 - Food and Drug Administration (1971) Advisory Committee on Protocols for Safety Evaluation, Panel on Carcinogenesis, "Report on Cancer Testing in the Safety Evaluation of Food Additives and Pesticides," Toxicology and Applied Pharmacology, Vol. 20 (1971), pp. 419-438.
 - International Agency for Research on Cancer, World Health Organization (1972) Evaluation of Carcinogenic Risk of Chemicals to Man, IARC Monographs, Vol. 1 (Lyon:

International Agency for Research on Cancer); and subsequent volumes.

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- National Research Council (1975) Pest Control, supra note 34.

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38 Mrak Commission (1969), Ibid., p. 464.

39 National Research Council (1970), supra note 37, p. 44.

40 Ibid., p. 45.

41 Ibid., p. 47.

42 Federal Insecticide, Fungicide, and Rodenticide Act, 7 USC 135 et seq (Supp. V 1975).

43 Federal Register, Vol. 39, p. 37265 (October 18, 1974).

44 EPA, "Respondent's Analysis of the Evidence, Summary of the Law and Argument," March 2, 1972, pp. 57-58.

45 The June 14, 1972 order of the Administrator was published on July 7, 1972; Federal Register, Vol. 37, pp. 13369-13376.

46 Ibid., p. 13375.

47 See the case study on this proceeding: L.E. McCray, "Mouse Livers, Cutworms, and Public Policy: EPA Decision Making for the Pesticides Aldrin and Dieldrin," this volume.

48 EPA, "Respondent's Brief, Proposed Findings and Conclusions on Suspension," September 16, 1974, pp. 28-57.

49 Ibid., p. 31.

- 50 Saffiotti's testimony had been cleared by those officials in NCI to whom he reported; see also, supra note 24.
- 51 Minutes of the Meeting of the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board, September 5, 1975, p. 5.
- 52 See supra note 43, p. 37267; the original reference was to an IARC report and to other WHO reports (supra note 37).
- 53 See also a treatment of the principles in the trade newsletter, Pesticide Chemical News, "EPA Setting Carcinogenicity Principles in Aldrin/Dieldrin Suspension Briefs," September 18, 1974, p. 27.
- 54 Letter from Lloyd D. Tepper to Senator Philip A. Hart, November 28, 1974. Questions posed by Hart to the Secretary of HEW were referred to Tepper and were part of a long-standing and general investigation of the effects on human health and the environment of pesticide chemicals. This particular debate was on the carcinogenicity of DDT and arose during hearings on vinyl chloride, at which Tepper was quoted as stating that there is no evidence that DDT is a carcinogen. (Tepper left FDA in 1976 to accept a position as Medical Director at Air Products and Chemicals, Inc., Allentown, Pa.)
- 55 See supra note 53.
- 56 Environmental Defense Fund, Inc. v. EPA, 510 F.2nd 1292 (D.C. Cir. 1975).
- 57 See supra note 42, section 16(b).
- 58 See McCray, supra note 47.
- 59 Under section 18 of FIFRA, supra note 42.
- 60 The pertinent documents for this decision were published in the Federal Register, Vol. 40 (April 8, 1975), pp. 15934-52. They are:
- March 14, 1975, Reasons for Denial, p. 15948.
- March 17, 1975, Statement of Reasons for Denial (including the report of a Special Review Group in the Office of Pesticide Programs), p. 15934.
- April 1, 1975, Supplemental Statement of Reasons for Denial, p. 15949.

- 61 Supra note 46.
- 62 Supra note 60, p. 15940.
- 63 Velsicol Chemical Corporation, "Velsicol's Motion to Submit Certain Relevant Questions of Scientific Fact to a Committee of the National Academy of Sciences," June 5, 1975.
- 64 Ibid., pp. 4,5; Tepper, supra note 54.
- 65 For example, see supra note 56 at 1300, footnote 21; see also supra note 52.
- 66 "Environmental Protection Agency's Memorandum in Opposition to Velsicol's Motion to Submit Certain Question to a Committee of the National Academy of Sciences," June 19, 1975. The publications cited on the question of benign and malignant tumors are:
- a) World Health Organization (1961), supra note 32.
 - b) World Health Organization (1969) Principles of Testing and Evaluation of Drugs for Carcinogenicity, Technical Report Series No. 426 (Geneva: World Health Organization).
 - c) Mrak Commission (1969), supra note 37.
 - d) L. Tomatis, C. Partensky, and R. Montesano, "The Predictive Value of Mouse Liver Tumor Induction in Carcinogenicity Testing -- A Literature Survey," International J. Cancer, Vol. 12 (1973), pp. 1-20.
- Those cited on the impracticality of setting of safe exposure levels for carcinogens are:
- e) The NCI and HEW approved statement of Umberto Saffiotti and testimony of Samuel S. Epstein.
 - f) Letter of the Secretary of HEW to Congress, June 14, 1974.
 - g) National Research Council (1975) Evaluating Chemicals, supra note 37.
- 67 EPA, "Motion to Take Official Notice of Certain Facts," June 24, 1975.
- 68 USDA, "Motion to Refer the Question of Whether the Present Uses of Chlordane and Heptachlor Constitute a Carcinogenic Hazard to Man to a Committee of NAS Scientists," July 11, 1975.

- 69 Velsicol Chemical Corporation, "Motion to Reconsider Order Denying Referral to a Committee or in the Alternative Motion to Submit Certain Relevant Questions of Scientific Fact to a Committee of the National Academy of Sciences," July 14, 1975.
- 70 EPA, Administrative Law Judge Herbert L. Perlman, "Order," cited in Velsicol motion, Ibid., p. 2.
- 71 Velsicol Chemical Corporation, "Reply of Petitioner, Velsicol Chemical Corporation, to Motion to Take Official Notice of Certain Facts," July 31, 1975.
- 72 Federal Register, Vol. 41, pp. 7552-7555, (February 19, 1976); the notice is dated July 29, 1975.
- 73 Ibid., p. 7553.
- 74 Ibid.
- 75 Ibid.
- 76 Ibid., pp. 7553, 7554.
- 77 Velsicol Chemical Corporation v. Train, Civil C-75-362 (W.D. Tenn. 1975).
- 78 EPA, "Clarification of Evidence Which May be Introduced in the Hearing on Suspension of Registrations of Pesticides Containing Heptachlor or Chlordane," August 6, 1975.
- 79 U. Saffiotti, "Draft for Discussion," August 25, 1975; see Table 4.
- 80 Letter from U. Saffiotti, NCI, to Jeffrey H. Howard, EPA, August 25, 1975.
- 81 For example, "The Blue Sheet," Drug Research Reports, Vol. 18, (September 17, 1975), p. 7; Pesticide Chemical News, Vol. 3, (September 3, 1975), p. 15.
- 82 EPA, "Preliminary Statement; Recommended Decision," December 12, 1975; Federal Register, Vol. 41 (February 19, 1976), pp. 7555-7572.
- 83 Ibid., p. 7565.
- 84 Ibid., p. 7567.
- 85 Ibid.
- 86 National Cancer Advisory Board, Subcommittee on Environmental Carcinogenesis, "Criteria for Establishing

the Carcinogenicity of Chemicals," (Working Draft--Not a Final Statement), November 11, 1975, p. 1; see also supra note 31.

- 87 Federal Register, Vol. 41 (February 19, 1976), p. 7567; see supra note 82.
- 88 Ibid., note 23.
- 89 EPA, "Decision of the Administrator on the Suspension of Heptachlor-Chlordane," December 24, 1975; Federal Register, Vol. 41 (February 19, 1976), p. 7573.
- 90 Ibid., p. 7574.
- 91 Ibid.
- 92 Environmental Defense Fund, Inc., v. EPA, 45 U.S. Law Week 2270; 9 ERC 1433 (D.C. Cir. 1976), p. 12.
- 93 Ibid., pp. 13, 14.
- 94 Ibid., p. 15.
- 95 EPA, Administrative Law Judge David H. Harris, "Order," August 20, 1975.
- 96 EPA, "Motion to Take Official Notice of Certain Facts," September 9, 1975.
- 97 EPA, "Supplemental Memorandum in Support of Respondent's Opposition to USDA's Motion to Refer the Question of Whether or Not the Present Uses of Mirex Constitute a Carcinogenic Hazard to Man to a Committee of NAS Scientists," September 18, 1975, p. 10.
- 98 EPA, Administrative Law Judge David H. Harris, "Order," October 23, 1975.
- 99 USDA, "USDA Reply to Respondent's Answer to USDA's Opposition to Respondent's Motion to Take Official Notice of Certain Facts," October 3, 1975.
- 100 EPA, "Supplemental Memorandum in Support of Respondent's Motion for Reconsideration of Denial of Respondent's Motion to Take Official Notice of Certain Facts," November 26, 1976.
- 101 EPA, Administrative Law Judge Harris, Oral ruling, January 5, 1976.
- 102 EPA, "Administrator's Decision on Interlocutory Appeal Affirming Denial of Respondent's Requests to Take Official Notice," April 22, 1976.

- 103 Ibid.
- 104 Federal Register, Vol. 40, (July 3, 1975), pp. 28242-28296.
- 105 Ibid., p. 28256.
- 106 Ibid., p. 28257.
- 107 Ibid., p. 28263.
- 108 Bob Wyrick, "EPA Officials Devised Cancer Tests on People," Washington Post, Thursday, June 23, 1977, p. A1; "EPA Proposed Carcinogen Test on Mexicans," Ibid., Wednesday, May 11, 1977, p. A1.
- 109 I wish to acknowledge the contribution made to the writing of this section by John E. Bonine, Office of General Counsel, EPA. Bonine gave me a preliminary draft of a paper tracing the term "principles" and reviewing some of the reports of expert committees.
- 110 Mrak Commission (1969), supra note 37, p. 465, text and footnote 2.
- 111 National Research Council (1975) Evaluating Chemicals, supra note 37, p. 150.
- 112 National Research Council (1975) Pest Control, supra note 34, p. 66.
- 113 Mrak Commission (1969), supra note 37, p. 11.
- 114 National Cancer Advisory Board (1977), supra note 31, p. 463.
- 115 Tomatis, supra note 37, p. 1.
- 116 U.S. Department of Health, Education and Welfare, Survey of Compounds Which Have been Tested for Carcinogenic Activity, Volumes I-III, (1974-1976), (Washington, D.C.: Government Printing Office).
- 117 The study was performed by the Litton-Bionetics Research Laboratories under contracts PH 43-64-57 and PH 43-67-735; see U.S. Department of Health, Education, and Welfare (1969), supra note 31, pp. 461-506; J.R.M. Innes, B.M. Ulland, M.G. Valerio, L. Petrucelli, L. Fishbein, E.R. Hart, A.J. Pallotta, R.R. Bates, H.L. Falk, J.J. Gart, M. Klein, I. Mitchell, and J. Peters, "Bioassay of Pesticides and Industrial Chemicals for Tumorigenicity in Mice: A Preliminary Note," J. National Cancer Institute, Vol. 42 (1969), pp. 1101-1114.

- 118 Use of this maximum tolerated dosage was the basis for criticism by one member of the Mrak Commission's Technical Panel on Carcinogenicity as being less than the maximum tolerated dose once the animals reached maturity. This, therefore, might mean that at higher dose levels carcinogenic effects could have been observed for more substances. Mrak Commission (1969), supra note 37, p. 483.
- 119 See Berenblum, supra note 36.
- 120 Ibid., p. 17; World Health Organization (1961), supra note 32, p. 9; Mrak Commission (1969), supra note 37, p. 487.
- 121 EPA, "Exhibit 40, Aldrin/Dieldrin Suspension Proceeding," pp. 7,8.
- 122 National Cancer Advisory Board, supra note 31, p. 461.
- 123 Food and Drug Administration (1971), supra note 31, p. 419.
- 124 Ibid., p. 420.
- 125 National Research Council (1959), supra note 37, p. 5.
- 126 Food and Drug Administration (1971), supra note 37, p. 420.
- 127 Mrak Commission (1969), supra note 37, p. 466.
- 128 World Health Organization (1961), supra note 32, p. 16.
- 129 U.S. Department of Health, Education, and Welfare (1970), supra note 37, p. 1.
- 130 Ibid., p. 6; See also World Health Organization (1964), supra note 14, p. 17; International Agency for Research on Cancer (1972), supra note 37, Vol. 1, p. 10.
- 131 National Cancer Advisory Board, supra note 31, p. 462.
- 132 L.G. Koss, "Precancerous Lesions," In: Fraumeni, ed., supra note 8, p. 85.
- 133 For an illustration of the confusion over the principles, see A.F. Plant, "A dangerous definition," Chemical and Engineering News, October 20, 1975, p. 4; Editorial, "Seventeen Principles about Cancer or Something," The Lancet, March 13, 1976, p. 571; Anonymous, "Scientific Judgment Must Prevail," Farm Chemicals, (August 1975), pp. 50-52.

- 134 World Health Organization (1974), supra note 37, p. 11.
- 135 Ibid., pp. 9,10.
- 136 National Research Council (1959), supra note 37, p. 15.
- 137 Ibid., pp. 31,32.
- 138 World Health Organization (1961), supra note 32; World Health Organization (1964), supra note 14; Mrak Commission (1969), supra note 37.
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- 1) American College of Veterinary Toxicologists
 - 2) American Dairy Science Association
 - 3) American Forage and Grassland Council
 - 4) American Meteorological Society
 - 5) American Society for Horticultural Science
 - 6) American Society of Agricultural Engineers
 - 7) American Society of Agronomy

- 8) American Society of Animal Science
 - 9) Association of Official Seed Analysts
 - 10) Council on Soil Testing and Plant Analysis
 - 11) Crop Science Society of America
 - 12) Poultry Science Association
 - 13) Rural Sociological Society
 - 14) Society of Nematologists
 - 15) Soil Science Society of America
 - 16) Southern Weed Science Society
 - 17) Weed Science Society of America
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APPENDIX A

COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY

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ON

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BETWEEN DECISION AND NON-DECISION: EPA'S
ASSESSMENT OF THE 'SUSPECT' INSECTICIDE CARBARYL

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I. OVERVIEW: A GUIDE TO THE ACTION

A. The Decision to be Made

Two investigations completed in the mid-1960s found about a 15 percent incidence of birth defects among puppies born to beagles that had received as little as 0.1 percent dietary concentrations of carbaryl. Studies in other species also seemed to demonstrate teratogenesis at higher doses. More recent studies indicate that carbaryl can combine with nitrites to form a compound that appears to be a potent carcinogen. EPA's policy task has been to determine whether these facts indicate human hazard requiring regulatory action.

EPA's assessment of carbaryl has not involved explicit consideration of which regulatory options would be appropriate. Under the 1972 Federal Environmental Pesticide Control Act (FEPCA), EPA can cancel some or all federal registration of products containing carbaryl if risks are judged to outweigh benefits. Short of cancellation, the Agency can require registrants to alter product label directions for use in order to limit human exposure. The Agency also can affect human exposure through the establishment of tolerances (allowable pesticide residues) in agricultural commodities.

Carbaryl was among 12 "suspect" pesticides that EPA formally reviewed between 1971 and 1975 as possible candidates for cancellation. The carbaryl review precipitated no regulatory action against carbaryl; nor has the Agency indicated that the chemical was exonerated. A decision not to decide was never made, however, and in fact for a period many thought that formal clearance was imminent. A determination is now said to be several months away.

B. The Action in Brief

Now ranked third among all insecticides in domestic use volume, carbaryl was reported teratogenic in an FDA study of beagle dogs published in 1968. A year later, the Union Carbide product was reported to be a teratogen in a mouse strain as well, and carbaryl was consequently listed among 19 pesticides (7 of them suspected teratogens) designated for additional study by the Mark Commission in its comprehensive review of pesticides and human health.

Following an appellate court opinion in early 1971 that encouraged the new Environmental Protection Agency to standardize its decisions about which pesticides, if any, should be taken off the market through cancellation, Administrator William Ruckelshaus announced a program of systematic reviews of suspect chemicals. Because it had appeared on the Mrak list, carbaryl was added to EPA's suspects list.

An expedited EPA literature survey on the toxicology of carbaryl was conducted in late 1971. No regulatory action was recommended at that time; final determination of carbaryl's teratogenic risk was to be deferred pending completion of a monkey study funded by Union Carbide. Studies using several other species had become available by this time, with positive results reported for chickens and guinea pigs.

Concern over possible teratogenic effects had, in part, led the Food and Drug Administration and later EPA to deny Union Carbide petitions for carbaryl tolerances for potatoes; in 1975, after the monkey tests proved negative, EPA granted the tolerance.

In 1973 and 1974 National Cancer Institute (NCI) studies showed that under certain laboratory conditions carbaryl and nitrites interacted to form nitrosocarbaryl, and that nitrosocarbaryl is a potent mutagen in standard bacteria tests. Researchers considered it not unlikely that further testing would show that nitrosocarbaryl induces tumors in test animals.

EPA's full internal review of carbaryl, about 375 pages in length, was completed in February 1975. While acknowledging that carbaryl is a teratogen in some species at relatively high dosages, the study team concluded there is no evidence of hazard to man. The nitrosocarbaryl problem was not mentioned. The review team leader formally recommended that all registrations of carbaryl be preserved. The only new restriction recommended was on sweet corn use in the vicinity of honey bees; carbaryl is thought to be a major pesticidal cause of bee kills.

No EPA action was taken following completion of its review of carbaryl. In late 1975 the suspect review program was phased out and the carbaryl matter was transferred to the group implementing EPA's program of reevaluating all pesticide products for reregistration according to general standards, as had been specified by FEPCA. It was expected within EPA that carbaryl would be cleared for reregistration by January 1976; snags developed, however, and the initial decision to challenge or clear carbaryl is now expected in Autumn 1977.

C. The Major Policy Issues

1. Does Carbaryl Present Teratogenic Risk to Human Females?

Birth defects have been reported in seven animal species. No-effect levels have been observed in some of these, however, leading some observers to conclude that a threshold effect is present. A key policy issue involved the assumptions used to extrapolate animal susceptibility to man. There has been dispute over the appropriate test animal for teratology studies; some scientists doubt that the non-human primate is the best test system for policy purposes, for example, and the dog data have been questioned because of differences between canine and human metabolism of carbaryl.

2. Does Use of Carbaryl Present Risk of Carcinogenicity to Humans?

The carcinogenicity of carbaryl itself has not been a central issue; several animal experiments (except for one non-cogent Russian paper) have reported negative results. However, the recent discovery of the mutagenicity of nitrosocarbaryl, coupled with indications that nitrosocarbaryl can be produced from carbaryl and nitrites in the laboratory setting, has raised new doubts. It is not yet known whether nitrosocarbaryl actually forms in the environment or in the mammalian body.

3. Are There Adverse Environmental Effects of Carbaryl Use?

In general, carbaryl has stimulated relatively few complaints on environmental grounds.

Carbaryl is highly toxic to bees, and, while as much an agricultural issue as an ecological problem, the vulnerability of the honey bee has received at least its due concern. Strengthening of bee warnings on carbaryl product labels has been suggested.

II. THE REGULATORY CONTEXT

A. The Pesticide Statute

1. Registration and Reregistration

All pesticides sold in interstate and intrastate commerce must be registered by EPA. The Agency registers each pesticide product (a product may be prepared by intermediary "formulator" firms and contain two or more active ingredients) for specific uses against specific pests

(e.g., against cutworms on field corn). An application for registration must include supporting data on the safety and efficacy of the product. Although a registration is nominally valid for only five years, historically there have been few fresh reviews of registration data because of the practice of automatically resetting the five-year "clock" whenever a registrant amended his application.

FEPCA stipulated the reregistration of all products four years after enactment.² In 1975 Congress extended this deadline by one year to October 21, 1977.³

The reregistration of some 40,000 pesticide products (including those containing carbaryl) will be conducted according to regulations issued in July 1975.⁴ These regulations introduce a modified "standards approach" to registration. If a chemical's toxicological properties are found to meet pre-specified criteria, a "rebuttable presumption against registration" (RPAR) is triggered. When this occurs, a full risk-benefit assessment begins on a use-by-use basis. Registrants may then attempt to persuade EPA that no unreasonable adverse effects will accompany the chemical's use.

The Agency is presently determining which chemicals will trigger RPARs. A list of 102 candidate compounds was released by Administrator Train in February, 1976;⁵ of these, 63 are suspected to be carcinogenic on the basis of animal testing; none of them are suspected teratogens. Many other chemicals, including carbaryl, were then listed as not yet evaluated against the RPAR criteria.

2. Cancellation and Suspension

Until the RPAR procedures were inaugurated in late 1975, EPA's assessment of carbaryl took place in the context of possible cancellation under FEPCA's Section 6.

A 1971 appeals court decision on DDT determined that a registrant carries a continuing burden of proof that his product meets statutory safety standards, and that the Administrator must initiate cancellation action if data indicate a "substantial question of safety"⁶ in the continued use of a pesticide. The court found, however, that a final cancellation decision "does not turn on a scientific assessment of hazard alone. The statute leaves room to balance the benefits of a pesticide against its risks."⁷ Under FEPCA, registrants who receive notice of cancellation are entitled to request a public hearing before an Administrative Law Judge.

3. Use Control

The pesticide law in effect until 1972 was essentially a labeling law, containing seldom-invoked provisions for outright product removal. The 1972 amendments provide two new regulatory controls short of proscription. First, pesticide registrations are to be divided into two use classifications, "general" and "restricted."⁸ Under the law, restricted pesticide uses are those for which actual applications can take place only under the supervision of (but not necessarily in the presence of) a certified applicator. Training and certification of these individuals can be conducted by state governments under programs approved by EPA. It is hoped that this mechanism will reduce accidents and unnecessary environmental contamination for the more toxic pesticides.

The second statutory innovation is a provision that makes pesticide misuse subject to civil and criminal sanctions; it is now illegal to "use any registered pesticide in a manner inconsistent with its labelling."⁹ While implementation is far from complete, this provision may eventually augment EPA's ability to control pesticide use through label specification.

4. EPA and Suspect Chemicals

Decision making for carbaryl has occurred under a succession of EPA programs designed to systematically review risks and establish relative action priorities for particular pesticides that are suspected of causing health effects and/or environmental damage. Among other functions, these programs represented EPA's "distant early warning" mechanism for the regulation of hazardous pesticides. Although originally intended to screen suspect chemicals for cancellation under Section 6, the programs were never coupled to the machinery for cancellation and their production rate was unimpressive. The special review program was eliminated in 1975.

III. THE CARBARYL STORY--TRAVELS IN ADMINISTRATIVE LIMBO

A. Carbaryl and Its Uses

1. Carbaryl and the Environment

Carbaryl's environmental persistence is much lower than DDT and the other chlorinated hydrocarbons and roughly the same as the popular organophosphates parathion and malathion. Union Carbide claims effective insect control for one to three weeks after application,¹⁰ the half-life of carbaryl on plants is but three to four days,¹¹ and one

study concluded that only about 1 percent of the applied product remained on the treated plant after 16 days.¹² (Users of the chlorinated hydrocarbon insecticides joke that carbaryl's trade name, Sevin, reflects the fact that carbaryl affords crop protection for merely seven days.) Carbaryl degrades quickly in water, and its half-life in soil is about one week.

The ecological hazard associated with carbaryl use is not large. Normal application rates produce only temporary effects on lower animal forms, and show no effects on reptiles, birds, or mammals in the treated area.¹³ Some aquatic species are affected at low concentrations (oysters and clams are killed in the range of two parts per billion [ppb] and trout in the range of two parts per million [ppm]),¹⁴ but a recent report states that no major wildlife kills have been attributed to carbaryl.¹⁵ Carbaryl is toxic to honey bees. Beekeepers have claimed that careless carbaryl use in the vicinity of pollination or honey production sites can be devastating.

As far as is known, carbaryl is seldom ingested by humans. The FDA's 1974 market basket study (chemical analyses of prepared meals typically consumed by a 150-pound teenage boy) identified carbaryl residues in but 8 of 360 sample composites (only one of them exceeding 0.1 ppm); six of these residues were found in 30 FDA samples of non-garden fruits.¹⁶ Few data are available regarding non-dietary human exposures. Human exposure may occur in the manufacturing plant, in product formulator facilities, and during field application (all of which fall under the jurisdiction of OSHA), as well as to farm workers entering previously treated fields and from home and garden use.

2. Human Toxicity

Studies indicate that when carbaryl is taken into the body, most of it is excreted within five days.¹⁷

Carbaryl's acute toxic effect is on the nervous system; it inhibits an enzyme that modulates nerve impulses, and carbaryl intoxication results in salivation, stomach pains, sweating, lassitude and vomiting. However, such symptoms are evidently only rarely encountered, as there are few reported serious accidental exposures. Union Carbide has stated that its Medical Department was informed of only 18 probable poisonings between 1960 and 1971.¹⁸ In only one known case has a person failed to recover from carbaryl poisoning; in 1968 a Hungarian scientist reported the case of a successful suicide by carbaryl ingestion.¹⁹ Carbaryl might still possess a clean mortality record had not attending physicians administered a treatment that is specifically contraindicated for carbaryl poisoning.

One index of carbaryl's relatively low acute toxicity is its "threshold limit value," the allowable air concentration in the workplace set by the American Conference of Governmental and Industrial Hygienists:²⁰

<u>Compound (selected pesticides)</u>	<u>TLV (mg/m³)</u>
Parathion	0.1
Aldrin, dieldrin	0.25
Heptachlor, chlordane	0.5
DDT	1.0
Carbaryl	5.0
2,4-D	10.0
2,4,5-T	10.0
Malathion	10.0

Subacute effects other than teratogenicity and carcinogenicity (detailed below) have not been scrutinized in the EPA reviews. Many human studies, including voluntary feeding experiments, report no adverse effects. Several standard tests have proved negative for mutagenicity, an exception being weak effects observed in the fruit fly. Human and animal studies have shown effects on the kidney of prolonged exposure to various levels of carbaryl (under 0.2 milligrams per kilograms of body weight [mg/kg] per day for humans). Learning was inhibited in rats fed 100 ppm/day and others receiving a single dose of 10 mg/kg.²¹ These data have not been considered important in EPA's policy reviews.

3. Production and Use

All carbaryl sold in the U.S. is manufactured in Union Carbide's production facility at Institute, West Virginia. Annual production is estimated at between 35 and 40 million pounds/year.²² About one-half this volume is exported. However, enough carbaryl is used domestically to keep it in third place among insecticides, and the domestic market, estimated at \$18 million,²³ is distributed as follows:²⁴

Agricultural Use	76%
Home/Garden	14%
Government	6%
Industrial/Commercial	4%
	<u>100%</u>

There are three major classes of insecticides: the chlorinated hydrocarbons and organophosphates each claim about 41 percent of the agricultural market, and the

carbamates account for 15 percent. Carbaryl accounts for over 70 percent of the volume of carbamate use.²⁵ USDA data for 1971 show carbaryl holding about 10 percent of the total agricultural insecticide market.²⁶

While not the only "broad spectrum" insecticide, carbaryl's spectrum may be the broadest. According to EPA tabulations, 240 registrations were held in 1973 for 1251 different products containing carbaryl.²⁷ Union Carbide reports that the registrations cover use on 85 crops against 160 insects.²⁸ Tolerances have been granted (most between 5 ppm and 12 ppm) for 70 commodities.²⁹ Only toxaphene (a chlorinated hydrocarbon) and methyl parathion (an organophosphate) outrank carbaryl for total domestic use, and cotton production alone accounts for three-fourths of toxaphene use and five-sixths of methyl parathion consumption. In contrast, carbaryl use is distributed among many crops, and all but one USDA crop categories show carbaryl among the top five sellers.³⁰

<u>Crop</u>	<u>Volume of Carbaryl Use</u>	<u>Carbaryl's Rank</u>
Peanuts	4.09 Million lbs.	1
Vegetables*	3.20 " "	1
Corn	1.65 " "	5
Tobacco	1.42 " "	1
Soybeans	1.35 " "	3
Cotton	1.21 " "	5
Grains*	1.09 " "	4
Fruits/Nuts*	.77 " "	2
Apples	.58 " "	2
Irish Potatoes	.36 " "	2
Citrus	.24 " "	2
Field Crops*	.22 " "	3
Hay/Pasture	.13 " "	1
Wheat	.11 " "	5
Alfalfa	.10 " "	9
Nursery/Greenhouse	.06 " "	2
	16.60 Million lbs.	

*not otherwise listed

Carbaryl has replaced DDT for several uses. Two areas where substitution has gained some public attention are in forest application against the gypsy moth (for which carbaryl was until recently one of two registered DDT substitutes) and in experimental use against the Douglas fir tussock moth. Tussock moth infestation in the Pacific Northwest necessitated a controversial EPA emergency exemption for DDT use in 1974. Subsequent trials of carbaryl against the forest pest, according to USDA, have provided "excellent results under operational conditions."³¹

Home and garden use, possibly the main source of potential exposure for the average citizen, is estimated at 1.5 to 2 million pounds/year.³² Over one-half of the products registered for home use are dust formulations³³ and are therefore readily subject to human inhalation.

Demand for carbaryl is robust. In fact, a 1976 press report indicated that Union Carbide was expanding its production capacity by 50 percent.³⁴

B. Chronology

1. The First Black Cloud: Teratogenicity Puts Carbaryl on the Suspect List

Carbaryl was first synthesized in 1953.³⁵ In its development phase, the chemical was known by its laboratory serial number, 7744, later abbreviated to the trade name Sevin.³⁶ Total development costs, according to Union Carbide, were \$2.5 million, including \$350,000 for toxicology studies.³⁷

Carbaryl was the first commercial success in the new carbamate class of insecticides. Its first federal registration and initial experimental sales came in 1958, and in 1959, the first year of commercial use, carbaryl production received patent 2,903,478.³⁸ Commercial expansion came rapidly; by 1964 carbaryl had risen to third among insecticides in volume of use,³⁹ and two years later carbaryl was already registered for use on 46 crops against 149 insects.⁴⁰

The door to limbo opened one day in 1966, when Union Carbide officials were contacted by FDA representatives. What the firm learned was an unpleasant surprise: carbaryl was associated with congenital malformations in beagle pups when pregnant females were fed as little as 6.25 mg/kg daily. Recollection of the 1962 European thalidomide tragedy, and its tangle of liability questions, impressed company officials with the gravity of the new findings.

The FDA study (eventually published in 1968⁴¹) had itself been an indirect result of the thalidomide disaster, which had stimulated FDA interest in chemical teratology. The carbaryl test was one of several conducted with chemicals that were in widespread use. Company officials surmise that the investigators selected carbaryl because a representative carbamate was desired; ethyl carbamate (urethane) was by then known to be teratogenic in mice and hamsters. Interest in carbaryl may have been reinforced by a 1965 report, cited in the FDA paper, indicating that carbaryl had adverse effects on egg production in house flies.⁴²

The FDA beagle study reported effects of treatment with carbaryl on the occurrence of "difficult" parturition, litter size, number of stillbirths, and pup survival rates.** In addition, the investigators identified congenital abnormalities as follows:**

<u>Dose (mg/kg)</u>	<u>Number Pups</u>	<u>Number Pups with Terata</u>	<u>Percentage</u>
50	7	1	14
25	23	3	13
12.5	78	14	18
6.25	34	3	9
3.125	39	0	0
0-Control	70	0	0
0-Breeding Colony	1753	3	0.1

Although 3.125 mg/kg was an apparent no-effect level for teratogenicity, there was no clear dose-response relationship above 12.5 mg/kg.

FDA then had statutory authority, later transferred to EPA, to set pesticide tolerances in food and feed crops. Reduction of these tolerances would have eliminated many carbaryl uses, so Union Carbide had persuasive inducement to initiate further teratogenesis testing when FDA suggested that such tests were important to its future policy on carbaryl tolerances. Rat studies were conducted at the Mellon Institute, a part of Carnegie-Mellon University that has had a continuing relationship with Union Carbide. Mouse, rabbit, monkey, and beagle studies were conducted at other locations under contract. All but the beagle study were ultimately reported as negative. Independent studies during this period, however, reported terata in three other species at higher doses.

The company-sponsored beagle study** began in late 1966. Fewer reproductive effects were observed than in the FDA work, although the numbers of stillbirths and pre-weaning deaths were higher in treated animals. Terata were reported as follows:**

<u>Dose (mg/kg)</u>	<u>Number Pups</u>	<u>Number Pups with Terata</u>	<u>Percentage</u>
12.5	57	7	12
5.0	46	7	14
2.0	33	0	0
Control	45	0	0

Results are thus consistent with the FDA study.

The contract researcher speculated that extraneous factors were accountable for the observed effects and concluded, "it is difficult to ascribe with any certainty any teratogenic effect due to the administration of 'sevin'; further study, with "perhaps ten times as many animals," was suggested.⁴⁷ Union Carbide chose not to follow this suggestion.

In late 1969, an HEW advisory commission under the chairmanship of Dr. Emil Mrak issued a comprehensive review of pesticides and health. Its assessment was based primarily on published studies. The Mrak Commission's Advisory Panel on Teratogenicity of Pesticides cited carbaryl as one of seven potential human teratogens.⁴⁸ This conclusion was based on the FDA beagle study, a mouse study reported by FAO/WHO, and a large mouse screening study conducted by Litton Industries' Bionetics Research Laboratory under contract to NCI. For each chemical on its Advisory Panel's list of suspects, the Mrak Commission advised that regulatory authorities undertake (1) "steps to minimize human exposure," and (2) "additional appropriate evaluative research...to guide future decisions."⁴⁹

The Mrak Commission also reviewed pesticides with respect to carcinogenicity. Thirteen chemicals were judged positive for tumor induction (and thus were also subject to the above recommendations); of 83 pesticides reviewed by the Commission's Advisory Panel on Carcinogenicity of Pesticides, carbaryl was one of only three that were exonerated as "'not positive' for tumor induction on the basis of adequate tests conducted in two or more species."⁵⁰

Lists of suspect pesticides predate the Mrak Commission. Such a list is indicated in the pages of Rachel Carson's Silent Spring,⁵¹ for example, and in 1963 a report of the President's Science Advisory Committee listed eight chemicals for which use restriction and regulatory review were recommended.⁵² Early concern, however, centered on compounds that, like DDT, are persistent, bioaccumulating chlorinated hydrocarbon insecticides. Aldrin, dieldrin, chlordane, heptachlor, endrin, and BHC/lindane were primary initial suspects. The Mrak Commission report broadened concern to other pesticide classes, and, for the first time, introduced suspect teratogens.

A month after EPA was created and had inherited the federal pesticide program from USDA and FDA, it received earnest guidance on its treatment of suspect chemicals from the U.S. Court of Appeals for the District of Columbia. Handing down its January 1971 opinion on an EDF appeal of USDA's refusal to hold DDT cancellation hearings, the Court ruled that such proceedings should begin whenever a

"substantial question of safety" arises.⁵¹ Furthermore, it urged the new Agency to actively consider establishing objective standards for initiating cancellation actions.

EPA Administrator Ruckelshaus responded in a March 1971 statement covering his cancellation decisions on DDT, 2,4,5-T and aldrin/dieldrin. Although asserting that it was impossible to establish general cancellation standards, he announced a program of internal reviews of pesticides identified as "possibly significant environmental contaminants:"

the function of the review is not to make another study of pesticides, but to identify which, if any, of the presently registered products present substantial questions of safety, questions which should trigger the administrative process of cancellation.⁵²

A new "Special Pesticide Review Group," led by senior toxicologist O. Garth Fitzhugh, met seven days later and assigned highest priority to six persistent pesticides, none of them suspected teratogens. Later in 1971 the suspect list was expanded to include all 19 compounds from the Mrak Report.

The Fitzhugh group decided to conduct cursory toxicological reviews of four suspected teratogens outside its regular review process. The four compounds were carbaryl, captan, folpet (all Mrak nominees) and difolatan, one of four pesticides added to EPA's suspect list by April 1972. These expedited reviews, each requiring about one man-month of effort, were said to have been ordered in the conviction that the exaggerated doses administered to experimental animals were far in excess of what humans might encounter, and in anticipation that a quick review might indicate that a full review was therefore unnecessary. None of the four was to be formally cleared, however.

The undated 17-page carbaryl review was entitled, "Carbaryl Insecticide: A Preliminary Report on Acute Toxicity and Mutagenic, Carcinogenic, and Teratogenic Effects." It summarized the major animal studies, (including Russian work reporting weakly positive results for tumorigenesis) and concluded that teratogenic effects had been shown in four species. The implication for human health:

...birth defects associated with oral ingestion of carbaryl have been reported. The possibility of similar occurrences in humans from exposures to carbaryl cannot be ignored...no means is known for projecting results from animal studies to humans.⁵⁵

There is no further discussion of what a human "safe dose" might be, the extent of human exposure, needs for additional data, and no indication of regulatory measures that might be invoked to restrict human exposure.

Participants' recollections of the next EPA actions are somewhat unclear. One official recalls that there was sentiment within the Office of Pesticide Programs (OPP) that carbaryl should be formally cleared or at least dropped from the suspect list. Higher officials were consulted, and an answer came down: EPA was to withhold a determination until an adequate teratology test in monkeys had been completed. Some OPP scientists, feeling that the monkey is not an appropriate test animal for carbaryl, regarded the decision as arbitrary and lacking scientific merit.

Producers of the sister suspects captan, folpet, and difolatan had also been asked to conduct monkey studies. The three fungicides, all chemically related to thalidomide (and like the sedative derived from phthalimide) gave negative results for teratogenesis at daily doses of up to 75 mg/kg (captan at that dose produced terata in rabbits) according to a study published in 1971.⁵⁶ Tolerances as high as 100 ppm on raw agricultural products remained in effect.⁵⁷ Monkey tests were also recommended by OPP personnel in 1973 in order to "close the books" on the teratogenicity of the Mrak suspect herbicide 2,4-D.⁵⁸

Union Carbide, however, was reluctant to initiate a primate study. Its explanation:

Dr. Fitzhugh stated that while he agreed with Union Carbide that the monkey was not a good species because of dissimilar metabolism, we should proceed with the testing. The reason for the delay was based on our belief that other test animals provided more reliable results in terms of attempting to extrapolate hazard to man.⁵⁹

In early 1973 Fitzhugh's review group was dissolved and its work was transferred to the new Criteria and Evaluation Division of OPP. At about this time, EPA responded to a House Committee that demanded to know why cancellation actions had been taken against only two chemicals (2,4,5-T and mercurials) on the Mrak list of suspect teratogens. The Agency reaffirmed that all would be actively reviewed for possible section 6 action:

EPA does, however, plan to initiate reviews of Captan, Folpet, 2,4-D, Carbaryl, and PCNB. The reviews are intended to initiate the administrative process leading to cancellation of use, if necessary."⁶⁰

The stipulated monkey teratology tests were ultimately conducted under Union Carbide contract at Albany Medical College. According to the firm,

The protocol for this study was designed by the authors and Union Carbide and was approved before the initiation of the work by EPA.⁶¹

No terata were found up to and including the highest dose tested, 20 mg/kg.⁶² The company incorporated the new results in its petition requesting that a tolerance for carbaryl on potatoes be established at 0.2 ppm.

In 1969, FDA had declined the grant such a tolerance, and EPA once again had refused in 1972. This time EPA's tolerance personnel conferred with the OPP scientists associated with the special carbaryl review and granted the amended tolerance. EPA's action gave Union Carbide confidence that the teratogenesis matter had been resolved, since the Agency had taken definite action allowing human consumption.

2. The Second Black Cloud: Nitrosocarbaryl

Teratogenesis, however, was no longer the sole issue. In a paper submitted for publication in May 1973, two University of Tennessee researchers reported on studies funded by NCI. The authors reported that several agricultural chemicals "have the potential to react with nitrite in acid solution to form N-nitroso compounds, many of which are carcinogenic."⁶³ The chemicals they had tested included carbaryl. Nitrosocarbaryl formed in laboratory conditions similar to those in the stomach (37 degrees C, pH range of 2.8 to 3.9). "Since nitrites are present in many foods," the authors commented, "a carcinogenic hazard to man could exist when food containing residues of certain agricultural chemicals is simultaneously present in the stomach."⁶⁴ A one-line footnote to the paper was foreboding: "Nitrosomethylnaphthyl-carbamate (nitrosocarbaryl) is a potent mutagen in the Haemophilus Influenza test system, as will be described in full elsewhere."⁶⁵ From other studies a partial correlation is known to exist between positive mutagenicity results in microbiological tests (such as H. Influenza) and the capacity for tumor induction in animals.

The full description appeared in Nature in February 1974. Nitrosocarbaryl was reported to be even more potent as a mutagen than the strong carcinogen nitrosomethylurethane. In the authors' view, nitrosocarbaryl was "likely to be a carcinogen" and "the stomach provides the acidic conditions for its formation."⁶⁶

Later, a third paper reported positive results for mutagenesis tests in two more microbiological systems. Its author notes the presence of nitrites in human saliva and raised the question of risk to those who are occupationally exposed to high levels of carbaryl.⁶⁷ In 1976 nitrosocarbaryl was also reported as "extremely potent" in the Ames test for mutagenicity.⁶⁸

3. EPA Completes Its Review

The new "Suspect Chemical Review" effort worked to complete reviews begun under Fitzhugh and also initiated a number of new reviews.

The carbaryl review was completed in February 1975. About 375 pages in length, it is entitled "Aspects of the Pesticidal Uses of Carbaryl (Sevin) on Man and the Environment," and is estimated to have required about 16 professional man-months to prepare. Its contents page is as follows:

Summary.	1
Introduction.	2
Chapter I - The Manufacture, Detection, and Formulation of the Carbaryl Insecticide Sevin.	12
Chapter II - Pharmacology and Toxicology of Carbaryl.	44
Chapter III - Fate of Carbaryl in the Environment.	169
Chapter IV - Residues of Carbaryl in Food and Feed.	285
Chapter V - An Economic Analysis of Apiary Losses Due to Carbaryl.	309
Chapter VI - Uses of Carbaryl.	325

Three OPP scientists contributed chapters - a biochemist (the team leader) wrote Chapters I, II, IV, & VI, a wildlife biologist Chapter III, and a junior economist Chapter V. As can be surmised, the work does not make for absorbing reading; it is a study-by-study compendium of what is published about carbaryl, described by the team leader as "a ten-foot stack" of paper.⁶⁹ Union Carbide contributed information to the study, chiefly in three areas; worker health reports from the manufacturing facility, unpublished

toxicology reports performed under contract, and data on carbaryl's end uses.

There is no attempt to balance risks and benefits or to assess policy implications in the document.

There is no mention of the nitrosocarbaryl matter. The project leader explained why it is absent: "We missed it."⁷⁰ The section on carcinogenicity cites only the discredited 1970 Russian study's findings of very weak tumorigenicity in rats.⁷¹

As for teratogenicity, information in the review is organized in an unusual fashion. The introduction to the chapter on toxicology contains the statement, "in appropriately designed studies, no teratogenesis has been demonstrated."⁷² The chapter's section on teratology contains no further discussion of what makes for an "appropriately designed" study; it simply reviews the monkey data, two guinea pig studies, and three rat studies that had reported negative findings.

The FDA beagle study that had triggered the original concern is discussed in the environmental effects chapter under a section labelled "Toxic and Teratogenic Effects on Livestock."⁷³ There is no reference to published studies of positive findings on mice, rats, and gerbils. Citations for the Bionetics mouse study are absent.

The team leader's separate position paper, "Suggested Actions on the Pesticidal Uses of Carbaryl" (undated), oddly, gives a clearer picture of the state of understanding about teratogenicity. "Teratogenic effects," he summarizes, "have been observed in guinea pigs, dogs, mice, and chickens."⁷⁴ Synopses of the FDA dog study and the FAO/WHO mouse study are presented. There is no discussion of the choice of test animals. The memorandum's conclusion #4:

Carbaryl is a teratogen. However, the conditions under which teratogenic effects have been demonstrated are not likely to be encountered under recommended conditions of use.⁷⁵

Hinted at, but unarticulated in this treatment, is the concept of a "safe exposure level" for carbaryl. While data on low dietary exposure levels to consumers are adduced, there is no reference to any problem of exposure to field workers or home users exceeding the implicit safe dose of carbaryl.

Regarding carcinogenicity, a sentence in conclusion #6 reads, "Effects observed in subacute toxicity studies indicate carbaryl is not a carcinogen."⁷⁶

The memorandum's recommendations:

1. Retain all uses of carbaryl presently registered.
2. Those uses on sweet corn which are likely to contribute to mortality of honey bees should be restricted to certified applicators. However, in order to retain the benefits of this use the classification should be performed on a regional basis.⁷⁷

The position paper is addressed to Leonard Axelrod (now deceased), Director of the Criterion and Evaluation Division. Its disposition within EPA is not known, as inquiries result in circular referrals. Those involved in the review assume that it was transmitted to the Deputy Assistant Administrator's office, if not higher. Except for the tolerance decision, there was no regulatory action on carbaryl in 1975.

In late 1975 the Suspect Chemical Review program was terminated.⁷⁸ Its review functions were transferred first to a new intraagency Suspect Chemical Review Committee and then three months later to a new Office of Special Pesticide Reviews (OSPR) established outside the Criteria and Evaluation Division in December 1975. OSPR is implementing the procedures for reregistration and is assessing the inherited suspect chemicals that are found to trigger the new RPAR procedures.

4. Carbaryl and the New Order

Decisions as to whether carbaryl (and 9 other well-studied chemicals inherited from the dismantled suspect chemical program) would be cleared or challenged were first scheduled by OSPR for January 17, 1976;⁷⁹ then the end of February;⁸⁰ then March 15.⁸¹

When, in February 1976, EPA listed the RPAR status of all active pesticide ingredients, carbaryl, then completing its fourth year in special review, was listed among chemicals that had not been evaluated according to the new criteria for triggering RPAR's. In April an OPP official indicated that carbaryl would soon be the first chemical to complete OSPR review, and he speculated that it would be cleared.⁸² Later, the decision on carbaryl re-scheduled for November 1976. In December 1976 the target for decision was moved to May 1, 1977.⁸³ At present, some in EPA expect to reach a decision by October 1, 1977, but others favor a six-month extension to allow time for Union Carbide to perform relevant new studies.⁸⁴

The new OSPR procedures involve formal intraagency coordination similar to (but distinct from) the Working Group-Steering Committee process used for most other EPA regulations. A Pesticide Chemical Review Committee, comprising representatives of the major EPA offices, monitors the work of a number of work groups (also representative in nature) that are assigned to specific chemicals. The group reviewing carbaryl has, in response to the active interest of members from the Office of Planning and Management, Office of General Counsel, and Office of Research and Development, begun a series of new fact-finding initiatives. It is generally thought that the renewed interest in carbaryl expressed in this group diverted OPP from the widely expected clearance of carbaryl in 1976.

The study team has turned over several new leaves. Available reports on animal teratogenicity have been reviewed by the teratologists in the Agency's Office of Research and Development and outside the Agency. The group requested that a qualified pathologist review slides from an earlier mouse feeding study for carcinogenicity. It has retained a consultant to assess the critical dog metabolism study and it may underwrite a new one. It has focused concern on possible hazards from home and garden use of carbaryl, and has, for the first time, undertaken steps to estimate human exposure from this use.⁸⁵ Asked about the value of the earlier carbaryl review, one OSPR official mused, "Well, it was some use as a bibliography."⁸⁶ EPA has also asked the FDA to include monitoring for nitrosocarbaryl, among many suspect compounds, in its Market Basket analysis;⁸⁷ if implemented, this search may indicate whether humans are regularly exposed to nitrosocarbaryl that forms outside the body.

If the ultimate decision is to issue an RPAR for carbaryl, the burden will fall on registrants to prove that its benefits outweigh risks on a use-by-use basis. If, following this review, EPA still refuses to register carbaryl, Union Carbide or other registrants are free to request a full adjudicatory hearing. A decision to reregister carbaryl is also subject to challenge by environmental groups, which would also lead to a public hearing. Thus, whatever the long-delayed decision is, it may yet be years before the book closes on carbaryl.

The large carbaryl review is currently being edited for publication. One difficulty in this process is the necessary excision of information supplied by Union Carbide under an assumption of confidentiality. Chapter VI, on carbaryl uses, and Chapter III, on toxicology, must be entirely rewritten, the latter because it is felt to fall below the professional standards of later reviewers.⁸⁸ The new version will no longer classify the beagle dog as livestock.

5. Still Hazy After All These Years: The Carbaryl Case as Public Policy

All in all, the carbaryl story is a somewhat depressing object lesson in the regulation of suspect chemicals. One might speculate that Union Carbide, at least, was satisfied by years of status quo that kept its product on the market. The truth is more complicated. The company observes that during its tenure on the suspect list, carbaryl products were granted new and amended registrations, and, eventually, new tolerances. In Union Carbide's view, each time EPA officials acted they were "tacitly affirming their acceptance of the product as effective and without unreasonable adverse effects when used as directed. This is not indecision or non-decision, this is positive product acceptance."⁸⁹ Still, the company is eager for a more definitive formal clearance. It was agitated by the dilatory handling of the carbaryl review itself, and feels that the enduring shadow of doubt has represented an unfair commercial disadvantage for a chemical that, it contends, is surely safer than competitive products.

It is impossible to assess whether the decision delay on carbaryl is in the public interest; that determination depends on the relative risks and benefits of carbaryl use, which remain shrouded in uncertainty. What is clear is the failure of EPA's regulatory program to elucidate those risks and benefits, particularly since 1970. In the late 1960's the company estimates it spent from \$1 to 1.5 million on the question of animal teratogenesis.⁹⁰ While not a negligible sum, this research left yawning information gaps on the question of human health hazard. For example:

- Is carbaryl teratogenic in beagles by inhalation (the route of human exposure from home and garden use)? At what concentration?

- What is the average level of human intake from home and garden use of carbaryl? For agricultural workers re-entering carbaryl-treated fields?

- Can we identify a specific carbaryl metabolite in the beagle that is associated with terata? If one is found, is it a human carbaryl metabolite as well?

- Is nitrosocarbaryl ever found in the environment? In humans exposed to its precursors?

These may not be the right questions (and their answers will not be cheap), but the real point is that, after the monkey study request, almost no active inquiry appears to have occurred until recent months under OSPR. Ironically, OSPR now finds itself constrained in specifying further

clarifying Union Carbide studies by internal pressures for a decision before such studies could be concluded.

Quite aside from the health questions, there has been virtually no analysis of carbaryl's benefits to users during the long review period, and, should a formal risk-benefit analysis be required, it will start from scratch on the benefits arm of the scale. Some may see this as a peculiar situation, given the pervasive emphasis in FEPCA on balancing risks against benefits.

Furthermore, the bulky carbaryl review did not focus the policy questions in a way that could guide further inquiry; for instance, the relative emphasis on honey bees and neglect of home/garden uses seems rather bizarre in retrospect. It should be noted that much of the critical risk information came by chance. For example, funding of the FDA beagle study and the nitrosocarbaryl studies had no direct linkage to ongoing regulatory programs.

The handling of carbaryl failed to advance policy formulation for other suspect chemicals. At its best, case-by-case decision making can expedite the formulation of general policy; the Agency's treatment of aldrin/dieldrin was exemplary in defining general "cancer principles" that were then written into the new registration regulations. The carbaryl case brought no analogous advances for the teratogenesis or the nitrosamine issues. The Agency still has not determined what principles should guide the selection of a test animal for teratogenesis study, nor has it established methods for calculating an "acceptable" level of exposure for a known animal teratogen. Instead of using the nitrosocarbaryl question to force the much larger general nitrosamine issue, the Agency has appeared to have relied on the hope that the eventual general policy solution would adequately fit the nitrosocarbaryl matter.

IV. TECHNICAL ISSUES IN DECISION MAKING

A. Carbaryl and Birth Defects

The dominant policy question during most of EPA's consideration of carbaryl has been than of possible teratogenic risk to pregnant women exposed to the insecticide. In some ways, regulatory concern with teratogenicity parallels that of carcinogenicity; the effects are delayed and tragic, the underlying scientific theories are elusive and fragmentary, and reliance on animal testing is both necessary and of debatable direct relevance to human risk.

1. Chemical Teratogens

Teratology (from the Greek root teras, meaning "monster"), is the study of congenital malformations due to anomalies in fetal organ development. It is a field still dominated by uncertainty. From its origins in the 1930s, the field was for decades of intellectual interest mainly to nutritionists and pediatricians.

About seven percent of all newborn babies, 200,000 annually, have physical birth defects⁹¹ (half requiring medical attention), as do about 17 percent of all stillbirths.⁹² The toll in human terms is high, including about 20,000 deaths/year (mostly in children under the age of 5),⁹³ the lifelong trauma of incapacitating physical and mental defects, and the incidence of "spontaneous" abortions. Until quite recently, however, the incidence of birth defects was not perceived as a public health problem. Then, in the early 1940's, dietary factors and German measles were proven teratogenic, and the tragic 1962 thalidomide episode (nearly 10,000 severely malformed babies) dramatically demonstrated the reality of chemical teratogenesis. At present 600 agents are listed as known animal teratogens and 25 (8 of them chemicals) are known human teratogens.⁹⁴ The March of Dimes attributes 20 percent of all birth defects to environmental chemicals.⁹⁵ Scientists in the field tend to be more conservative; one leading expert puts the rate at 2-3 percent (4,000-6,000 cases/year) for drugs and chemicals but ascribes 70 percent to still unknown causes.⁹⁶ It is not implausible that further knowledge will reveal a much greater environmental contribution to birth defects. This has been the case for cancer, for which 60-90 percent of all cases are now ascribed to environmental agents.

Study in the field of teratology is complicated by the variety of known causes (chemical, hereditary, radiation, maternal malnutrition, and maternal disease--e.g. rubella) and the variety of specific anomalies classed as "terata." Acceptable protocols for animal studies are still under discussion, as is the choice of the appropriate test animal in light of significant species-to-species variation in susceptibility (even thalidomide had limited effect in some test animals). The existence of threshold-level responses to chemical teratogens is suspected by many but is not accepted as dogma. Even if it is accepted, however, there remains the nettlesome problem of relating no-effect levels in test animals to acceptable doses for humans. Needless to say, policy making cannot await resolution of these uncertainties, and each question is unavoidably subjected to partisan debate when a question of regulation arises.

Amid the complexities and uncertainties of the field, the policy maker cannot expect science to light his path.

For example, a perceptible air of futility is found in the conclusion of one expert's recent overview of the field:

...despite all our best efforts, when we become confident in our ability to predict teratogenic liability, our pride will be trampled by another teratogen like thalidomide, for which man is the most susceptible species.⁹⁷

2. Teratology and Pesticides Policy

The fear that a pesticide would prove to be "another thalidomide" has pervaded pesticide reviews for more than ten years. The 1963 PSAC pesticide review recommended that teratogenicity studies be conducted in two species.⁹⁸ New pesticide registration requirements for teratogenicity studies were finally added in 1970, seven years after FDA required such testing in drugs.⁹⁹

The Panel on teratogenicity under the Mark Commission reviewed available published evidence in 1969 (most of which was termed scientifically "inadequate").¹⁰⁰ Of the seven pesticides that were indicated for special review, EPA was in the next eight years to initiate cancellation proceedings against only 2,4,5-T and mercurials. Hearings on the herbicide 2,4,5-T were interrupted after it was indicated that the toxic agent was not 2,4,5-T itself but a potent impurity, dioxin. Dow Chemical Company then claimed dioxin could be reduced to negligible amounts through change in production methods. Lengthy cancellation hearings on mercury pesticides were concluded in 1976 with a ban of many uses. Suspect chemical reviews were completed by EPA only for carbaryl; abbreviated reviews were also conducted for the 2,4-D and fungicides captan, folpet, and difolatan.

EPA has shifted positions in its treatment of suspect teratogens under its new registration procedures. The October 1974 proposed regulations for registration grouped teratogenicity with oncogenicity and mutagenicity as conditions that trigger an RPAR:

a. Chronic Toxicity. A rebuttable presumption against registration shall arise if the product ingredient(s), its metabolites, or degradation products: (1) are found to produce in laboratory or field conditions, any oncological effects, teratogenic effects, or multitest evidence of mutagenic effects....¹⁰¹

In the July 1975 final published version of the regulations, teratogenicity was separated from oncogenicity and (implicitly) moved to a new section. An RPAR is to be triggered by any compound that:

(A) induces oncogenic effects in experimental mammalian species or in man...or induces mutagenic effects, as determined by multitest evidence. (B) produces any other chronic or delayed toxic effects in test animals at any dosage up to a level, as determined by the Administrator, which is substantially higher than that to which humans can reasonably be anticipated to be exposed, taking into account ample margins of safety.¹⁰²

In early February 1976, the resignations of three high-level EPA pesticides lawyers was widely taken as a last-ditch protest against the Agency's perceived reluctance to act on suspect chemicals. The resulting public and Congressional reaction helped persuade EPA to release an interim list of 102 chemicals expected to trigger RPARs, 24 of which were attributed to "embryotoxicity" (all of these are mercurials) and six of which were listed as "dioxin," presumably because production processes may leave this potent impurity in the compound.¹⁰³ None are listed as suspected teratogens. Carbaryl, captan, and folpet were listed as not yet classified.¹⁰⁴

According to the EPA officials, the Agency maintains no current list of suspect teratogens. Lacking a policy determination of methods of calculating acceptable dose levels under the registration regulations, however, the list can only grow. In October 1975, the Rachel Carson Trust for a Living Environment submitted a list of 13 suspected teratogens (including carbaryl and the other six Mrak suspects) in Congressional testimony. The list was "based on tests in mammalian systems, usually rats or mice."¹⁰⁵ Among pesticide ingredients, only mercury had been confirmed as a human teratogen as of 1975.¹⁰⁶

3. The Teratogenicity of Carbaryl

Because of the nature of the carbaryl reviews, issues were not brought into contrastive relief by open public debate, and differing policy views were largely implicit.

The cautious policy position is inherent in the proposed version of EPA's criteria for the triggering of an RPAR: as with oncogenicity, any positive teratology test results (any mammal, at any dose, by any method of administration) would trigger an RPAR and thus necessitate a full review of benefits and risks. By this test, carbaryl would clearly have been designated for review on the basis of available data.

The opposite view is that no actual human risk can be inferred, as is carefully phrased in Union Carbide's promotional literature:

Reproductive experiments with SEVIN have been reported on various strains of rats and mice as well as on hamsters, gerbils, guinea pigs, rabbits, chickens, quail, monkeys, dogs, and sheep. Valid studies of this type using animals that are not dissimilar to man in metabolism of SEVIN and paralleling men's dietary inclusion route have shown no deleterious reproduction or teratogenic effects at, or reasonably above, the dosage levels previously demonstrated to be without ill effects in lifespan studies. (emphasis added)¹⁰⁷

a. The Experimental Data. The FDA beagle study, published in 1968, had been the initial warning signal. Following disclosure of these results, many followup studies were conducted. Not without encouragement from FDA and, later, EPA, Union Carbide supported many of these studies, eventually spending an estimated \$1.5 million on animal investigations.¹⁰⁸ While no systematic tabular summary of results was discovered in research for this case, available information indicates tests on twelve species. Birth defects (fetal malformation in the researchers' judgement at some dosages) were reported in seven of these:

<u>Species and Author</u>	<u>Sponsor (Publication Status)</u>
1. <u>Beagle Dog</u>	
<u>Positive</u>	
Smalley	FDA (Published 1968)
Imming	Union Carbide (Unpublished)
2. <u>Rat</u>	
<u>Positive</u>	
Collins	FDA (Published 1970)
<u>Negative</u>	
Weil	Union Carbide (Published 1971)
3. <u>Mouse</u>	
<u>Positive</u>	
Bionetics	NCI (Reviewed in Mrak Report, 1969)
FAO/WHO	
<u>Negative</u>	
Benson	Union Carbide (Unpublished)

4. Gerbil
 Positive
 Collins
 FDA (Published 1970)
5. Sheep
 Positive
 Panciera
 (Unpublished)
6. Chickens
 Positive
 Ghadiri
 (Published 1967)
7. Guinea Pigs
 Positive
 Robens
 FDA (Published 1969)
 Negative
 Weil
 Union Carbide (Published 1973)
8. Monkey
 Negative
 Coulston
 Union Carbide (Published 1974)
9. Rabbits
 Negative
 Shaffer
 Robens
 Union Carbide (Unpublished)
 FDA (Published 1969)
10. Swine
 Negative
 Smalley
 FDA (Published 1968)
11. Quail
 Negative
 DeWitt
 Dept. of Interior (Unpublished)
12. Hamster
 Negative
 Robens
 FDA (Published 1969)

At first reading, the evidence may appear weighty. However, the protocols of teratology testing were themselves in embryonic development in this period, and several of the "positive" findings are now deemed questionable for varying reasons. Some, (e.g. gerbils and rats) for example, found effects only at massive dosages of 5000 ppm and above. Large doses can have acute toxic effects on fetuses whose organs are already developed, as distinct from interference with the process of organogenesis, and results are therefore not defined as teratogenic. For the sheep study, two animals in a treated group of 23 (p was calculated at only 0.23) exhibited cardiovascular anomalies thought to be rare. However, one wonders whether the natural frequency of specific fatal birth defects could have been well characterized for non-laboratory animals. Data on guinea pigs were later questioned because there were toxic effects on the mothers, which may have altered fetal development. The Bionetics mouse work was questioned because treatment was by subcutaneous injection, rather than by feeding. In fact, although much human carbaryl exposure may be dermal or by inhalation, no pesticide has evidently been tested for teratogenicity in animals by these routes.¹⁰⁹ Obviously some general guidelines are needed.

The animal whose results were least vulnerable to methodological challenge was the one that started the effort: the beagle puppy. The only industry-sponsored test giving positive results was that for the beagle. An irony no doubt piquant to Union Carbide is that the most vulnerable species to carbaryl was one that the FDA investigator termed an "unusual" choice for teratology testing.¹¹⁰

b. Problems of Interpretation. One key question for policy making is the designation of the appropriate test animal. Some scientists argue that the beagle is decidedly the wrong species; this is because beagles metabolize carbaryl quite differently from humans.

Union Carbide contended that the rat was the best single test system. FDA and EPA, however, wanted to see monkey studies, an idea the company resisted. Chevron, the manufacturer of Mrak Commission suspects captan and folpet, had earlier completed primate studies as requested. Whether the insistence that Union Carbide follow suit was based on scientific arguments or on a "common sense" feeling that monkeys are most man-like is unknown; an EPA scientist is reported to have admitted the latter while reporting that a monkey test would have to be completed. One factor in the decision may have been that the monkey proved the best indicator of thalidomide's teratogenicity. In any event, the choice of non-human primates has eminent scientific proponents, including James G. Wilson.¹¹¹ Wilson has also indicated his belief that routine use of rodents as the

critical test species would have required banning of the human use of aspirin, cortisone, and dilantin, among other compounds.¹¹²

It eventually became clear that EPA would neither clear carbaryl nor grant residue tolerances unless the test were undertaken, so Union Carbide acceded to the request. An 80-monkey study was initiated at feeding levels 10, 100, and 1000 times the FAO/WHO acceptable daily intake level (then .02 mg/kg) for humans. When the negative results became available, the potato tolerance was granted and the internal review of carbaryl resumed.

The EPA carbaryl review contained no discussion of the animal choice question. The position document does state, "teratogenic effects have been observed in guinea pigs, dogs, mice, and chickens,"¹¹³ but does not delve into the question of comparative metabolism in order to pave the way to the conclusion that no human hazard exists. The document does appear to give the negative monkey findings special weight: "the results of that (rhesus monkey) study indicated that present registered uses of carbaryl were not likely to induce teratogenic effects on humans."¹¹⁴

A second crucial problem of interpretation lies in the establishment of safe levels of exposure to teratogens. As we have seen, the new registration regulations countenance the designation of acceptable exposure levels to animal teratogens. In addition, it was the feeling of many of the scientists associated with the carbaryl review (although the review itself does not cover the point) that the fatal flaw in most of the teratology studies was the unreasonably high dose levels tested; most Americans, after all, probably only rarely experience any intake of carbaryl.

Even for results reported as positive, a no-effect level was observed. For the beagle tests, no effects were observed at 3 mg/kg and 2 mg/kg. These levels are 200-300 times the present FAO/WHC acceptable daily intake (0.01 mg/kg), which itself is at least 10-30 times higher than dietary exposure as reflected in market basket analyses.

The problem remains, however, of relating the no-effect level in dogs to humans. No branch of science will soon elucidate this extrapolation. The carbaryl review does not highlight or examine the no-effect or safe-dose questions, nor has EPA since developed a policy for establishing safe levels for teratogens under its new criteria. The Agency will, without doubt, be forced to establish such policy in order to reregister suspected teratogens. This may turn out to be another stumbling block for carbaryl. Assume, for example, that the Agency determined the acceptable human dose to be 0.01 of the no-effect monkey dose. The highest dose used in the carbaryl monkey study was 20 mg/kg, so the

acceptable dose, 0.2 mg/kg, is exceeded tenfold by the firm's estimation of the exposure of a careless and lightly-clad home gardener.¹¹⁵

A NIOSH contractor completed a review of the occupational exposure standard for carbaryl in September 1976. Its prudent conclusion is that

The lack of carbaryl-related teratogenicity in other species [than the beagle] does not now warrant the conclusion that carbaryl should be classified as a teratogen in human.¹¹⁶

The document does, however, call for additional research on the mechanism of beagle teratogenicity and on human epidemiology of terata in mothers exposed to carbaryl.¹¹⁷

B. Carbaryl and Cancer

1. Carbaryl as a Carcinogen

The carcinogenicity of carbaryl itself was never a central issue. The 1969 Mrak Report found only three pesticides for which adequate data existed to support a finding of non-carcinogenesis: one was carbaryl.

In 1970, Russian scientists reported what appeared to be tumor induction in rats. However, incidence was not particularly high (6 percent and 4 percent in surviving treated animals, and 2 percent in control animals). Today, these findings have been largely written off as aberrant. Part of the reason for this is general dubiety about the standards of Russian biology; one scientist terms the field "still in the Stone Age" in the U.S.S.R. The clinching argument, however, was that the study had never been replicated, and in fact another Russian paper reported negative results from a rat oncology study. There is speculation that the test sample of carbaryl was contaminated

EPA's carbaryl review gives the entire Russian literature on carbaryl special handling, summarizing the results of available Russian papers on carcinogenicity and other tests in an appendix to the chapter on toxicology. Four reasons for this special treatment are offered.¹¹⁸

- 1) "Translations of most of the Russian articles are not available."
- 2) Inconsistencies of interpretation in different reports of the same studies are found.

3) The source and purity of the carbaryl are seldom reported.

4) The available reports omit essential experimental details.

2. Nitrosocarbaryl

Considering that the possible risk is the dread disease cancer, reaction to the nitrosocarbaryl findings described above was moderate. Union Carbide was unaware of the tests until they were published, and even in mid-1976 key company representatives were unfamiliar with the details of the nitrosocarbaryl studies. EPA's carbaryl review, completed some 20 months after the formation and mutagenicity of nitrosocarbaryl were first announced, contains no reference to the implied risk. Appreciation of the problem seems not to have irrupted into EPA at all until late 1975.

It does not render decision making for carbaryl any less difficult, but it is likely that nitrosocarbaryl represents a small part of the general problem of environmental nitrosamines. As a class, nitrosamines are potent carcinogens (90 of 120 tested have proved positive).¹¹⁹ They have been found in cigarette smoke, urban air samples, meats, cheese, toiletries and packaged pesticides. They form in reactions between nitrites and a large number of nitrosable compounds like carbaryl. As of 1975, 10 pesticides besides carbaryl had been shown to be nitrosable.¹²⁰ Union Carbide asserts that 80 to 100 other pesticide active ingredients are potential precursors of nitroso compounds.¹²¹ EPA has recently indicated that as many as 1500 pesticide registrations may involve potential precursors.¹²² An alternative way to combat in vivo nitrosation, in theory, would be to restrict nitrite intake. One account reports that about two-thirds of the nitrite entering the stomach is in saliva, produced by bacterial reduction of nitrates (most of the rest is in cured meats).¹²³ The major source (80 percent) of dietary nitrates is in vegetables,¹²⁴ so the opportunity to limit stomach nitrites is evidently limited.

The key policy question is whether nitrosocarbaryl actually forms, either in vivo or in the environment. There is no present evidence that it does. In fact, a later independent study indicated that mice fed nitrites and carbaryl did not develop a significant increase in tumors. On the other hand, there is no firm assurance that nitrosocarbaryl never forms. Union Carbide now emphasizes that lack of evidence: "We object to references that nitrosocarbaryl is a mutagen/oncogen on the basis that the formation of this compound in the digestive tract of man has not been demonstrated."¹²⁵ It has been pointed out that,

since nitrites are ubiquitous, any significant health problem would already have surfaced by now in studies of Union Carbide plant workers, who were long exposed to elevated levels of carbaryl. Furthermore, it is argued the numerous long-term carbaryl feeding studies show no evidence of oncogenicity in animals.

These observations, however, are not beyond refutation. Many feel that, based on past results with compounds similar to nitrosocarbaryl, it is only a matter of time until positive findings of oncogenicity appear. There is no assurance that nitrosocarbaryl doesn't form in the environment. Company plant workers' intake of carbaryl by inhalation and dermal penetration, not ingestion, so their exposure may signify little; in addition the absence of employee cancer may indicate merely that the workers' latency period has not passed. The lifespan carbaryl feeding studies may well have involved proportionately less exposure to nitrates and nitrites than humans experience in their diet.

Obviously a sound policy determination requires more conclusive evidence on the actual formation and fate of nitrosocarbaryl in mammals. Union Carbide is not known to have funded any work on the nitrosocarbaryl question. Those asked knew of no EPA-supported studies in this area either.

Perhaps as significant as consumer safety (and less fully appreciated in EPA reviews) is the problem of plant workers, formulator employees, applicators, and field workers whose occupational exposure to carbaryl exceeds the average diner's. NIOSH estimates that 100,000 Americans have occupational exposure.¹²⁶

c. Carbaryl and the Environment. As a broad-spectrum insecticide, it is not surprising that carbaryl affects beneficial insects as well as those with pestiferousness. The honey bee has been the main object of ecological concern. The stakes, however, were less a matter of environmental disturbance than threat to a \$105 million (1973) honey business and as many as 90 crops with a value of \$1 billion¹²⁷ that depend on the bee for pollination.¹²⁸

Carbaryl is thought to be the major cause of bee kills by pesticides. Under an act of Congress beekeepers are indemnified for losses due to pesticide use. The EPA review's chapter on bees analyzed indemnification payments and found that carbaryl damage accounted for almost 30 percent of the total awarded. Nearly three-fourths of the damage was due to carbaryl use on sweet corn.¹²⁹

Actually, carbaryl is less acutely toxic to honey bees (which forage in corn fields only if preferred pollen sources are unavailable) than several other common

insecticides. Ironically, higher potency would probably have been a happier circumstance for carbaryl registrants. Lacking "knock-down" potency, carbaryl permits contaminated field bees to carry the pesticide back to their hives, further affecting the food supply of the hive's next generation.¹³⁰

Union Carbide put bee warnings on carbaryl labels prior to 1970. However, losses persisted. At one point in the discussion on the bee problem EPA officials speculated that a solution would be for the company to withdraw its sweet corn registration altogether. The EPA review recommendation represents a middle course, calling for corn use only under the supervision of qualified applicators. This restriction, it was felt, would insure that nearby beekeepers would be informed before application and could take precautionary measures. EPA did not act on this recommendation. Union Carbide feels that the honey bee problem may have been overstated in any event because the Indemnification Act gives beekeepers incentive to blame carbaryl for all kills, regardless of their true cause.

Besides bees, no other environmental risks were given detailed attention in the carbaryl reviews. There have been some questions raised concerning carbaryl's effects on aquatic organisms. Crustaceans are known to be sensitive, and 1 ppb was found to interfere with egg development in clams.¹³¹ However, these effects have not drawn the fire of environmentalists, partly because carbaryl degrades quickly in water.

A major pesticide use affecting aquatic contamination is forest pest control. Carbaryl has been used against major forest pests including the gypsy moth, spruce budworm, and the Douglas fir tussock moth. It happens that carbaryl is a DDT substitute for control of these forest pests, and some of the high politics and emotionalism which attended decision making for DDT spill over into the contemplation of forest uses of carbaryl. Anti-DDT forces find themselves defending carbaryl, while DDT defenders find themselves emphasizing carbaryl's adverse environmental effects. After an arduous struggle, carbaryl was registered for spruce budworm control. It is not registered for tussock moth control; however, field tests conducted in conjunction with EPA's celebrated March 1974 emergency exemption for DDT use against the tussock moth show carbaryl also giving "excellent results," according to USDA.¹³² Those interviewed indicated that decision making for forest pest control involved formidable political forces; however, these forces seem not to have affected the carbaryl review.

V. THE GENERAL PROBLEM IN REGULATING SUSPECT CHEMICALS: UNREALISTIC HOPES

A. Program Slippage

There is no reason to think that EPA's treatment of carbaryl was atypical. It was, after all, but one of 25 chemicals on EPA's 1971 list of suspects (only two of which have been ultimately decided), and about 70 other pesticides are now thought to have serious enough adverse characteristics to require consideration of issuing RPARs. Nor is there indication that the potential hazards associated with carbaryl are worse than the average suspect's. In fact, one formal potential-hazard ranking scheme placed carbaryl tenth on a list of widely-used pesticides (and sixth among the listed insecticides);¹³³ asked to provide action priorities for 45 RPAR candidates in 1976, EPA's Science Advisory Board (SAB) placed 24 of them ahead of carbaryl.¹³⁴ Fifth on SAB's list was toxaphene, a persistent, bioaccumulating chlorinated hydrocarbon that is by some margin America's best-selling insecticide. Toxaphene, already considered a "high-priority" Fitzhugh Committee suspect carcinogen in 1971, was, like carbaryl, the subject of a 1975 review monograph, but it did not attract much attention (or new carcinogenesis experiments) until EPA's receipt of long-awaited positive NCI test results led to quick issuance of an RPAR in May 1977.¹³⁵

EPA's two basic strategies for dealing with problem pesticides, the suspect chemical reviews and the reregistration program, have both been marked by overambitious plans and troublesome practical obstacles.

Administrator Ruckelshaus' court-inspired March 1971 announcement of "active internal review" of potential cancellation subjects was followed by energetic plans. A "crash" recruitment effort was foreseen to fill 19 new positions under the new Fitzhugh group, and a production rate of one review per month was anticipated.¹³⁶ (Had this rate been realized, the entire original suspect list would have been completed in 1973.) The group's unambiguous charter: "To identify which, if any, of the presently registered products present substantial questions of safety which should trigger the administrative process of cancellation."¹³⁷ The group knew it had an imposing task: roughly one of every five registered products, it was calculated, contained an ingredient from the Mrak suspect list that was adopted as the Fitzhugh group's initial agenda.¹³⁸

EPA memoranda written in 1973, 1974, and 1975 describe an expected production rate of 6 to 12 reviews annually.¹³⁹ At the midpoint of the program, the number of suspects exceeded 100.¹⁴⁰

When, in December 1975, the suspect chemical program was merged with the reregistration effort, only 12 full reviews had been completed in nearly five years. In only two cases (mercury and heptachlor/chlordane) had a review been followed by cancellation action, and it is doubtful that the reviews influenced policy for even those two cancellation cases. Of the 19 Mark Committee suspects, seven were eventually reviewed by EPA.

Several factors may have affected the pace of the suspect chemical effort. Environmentalists might argue that the problem was that program personnel were industry-oriented. Indeed, many CPP staff members had come to EPA from parts of USDA that were as interested in promoting pesticide use as controlling it, and about 60 percent of the professionals in OPP have agricultural backgrounds.¹⁴¹ However, there is no indication that the review program was willfully subverted, and while designation of pro-pesticide reviewers might have affected the nature of the monographs, it should not have affected the number of reviews completed. Another complication was organizational instability; control over the program shifted three times before it was finally given to OSPR in 1975. However, whether these changes represent a cause or an effect of unimpressive performance is not clear. A third factor is the lack of resources. Review teams never approached the planned staff strength. This explanation is the one favored by the three Office of General Counsel (OGC) lawyers who in 1976 resigned in protest of EPA inaction on hazardous chemicals:

The data underlying the registrations of a substantial number of widely used pesticides do not support their safety as required by law. Although EPA has publicly itself to review this data, no priority authorization for review by more than a skeleton staff has been given.¹⁴²

The fundamental impediment, it can be argued, was indeed a lack of resources, but not those of OPP; the reason that reviews only slowly appeared was that the Agency could never sustain more than about one and a half major cancellation hearings at any time. The four major EPA cancellation actions absorbed large budgets and took years to complete (for instance, the elimination of the insecticides aldrin and dieldrin consumed 4 1/2 years, including a full year of formal hearings, and cost the Agency over \$5 million¹⁴³). One OPP alumnus indicates that the review groups were asked to throttle production in 1972 because OGC had found itself unable to keep up with the monographs.¹⁴⁴ If there is a single best explanation for the fitful progress of the Agency's suspect pesticide evaluation effort, it lies in the statutory provision of full hearings on each cancellation coupled with limited EPA legal resources.

Section 6 cancellations were not the public's final safeguard against problem pesticides--FEPCA's reregistration requirement was. That was the device that, once implemented, would provide blanket compliance with modern testing requirements (scheduled for October 1976) for generations of pesticide products. Reregistration was an immodest task, for EPA's pesticide program was simultaneously expected to implement many other novel statutory requirements and to maintain its continuing load of registration actions.

Superficially, at least, there was no hint that the reregistration deadline was unattainable for the first years under FEPCA. New regulations incorporating general standards for registration and the RPAR scheme were promulgated in 1975, not outrageously later than was specified the statute. In 1974 EPA vainly asked OMB for 100 additional positions for the reregistration effort, but even in December 1975 the Agency gave assurance that the statutory goal (by then gratuitously extended to October 1977) could be met.¹⁴⁵

In the following month, disaster struck. In the words of EPA pesticide chief Edwin Johnson:

...in 1976, we received some new information. Information which was startling and disconcerting. Information which not only could affect our future plans, but which also cast doubt on our past performance. Information which struck at the very foundation assumptions of the registration and reregistration process.¹⁴⁶

The news was that the existing registration files were discovered to be incomplete, unreliable, and chaotic. The data file, described as a half mile of material,¹⁴⁷ would require inch-by-inch verification.

Closer review revealed that adequate data had been supplied for less than one-half of the registered pesticides; carcinogenesis data alone was missing for one-quarter of the chemicals.¹⁴⁸ An additional surprise was that where data were available, the degree of potential hazard was surprisingly high; of the first 650 pesticides completing preliminary review, only 180 could be cleared for reregistration.¹⁴⁹

These dismayingly discoveries attracted legislative reproach. An October 1976 House report concluded starkly that "EPA's regulatory policy is failing to adequately protect the public,"¹⁵⁰ and a well publicized Senate staff report released two months later¹⁵¹ was so critical of management deficiencies in pesticides that one EPA official

termed it "probably the most devastating report to hit EPA since it was formed."¹⁵²

Belatedly, the Agency admitted that it could not satisfy the October 1977 reregistration deadline. In fact, this year the Agency indicated that about 600 more staff positions would be required to finish the job by 1982, and, with the expected limit of 100 new positions, that the job may not be finished for a decade beyond that.¹⁵³ The Agency stresses that the adverse impact of this slippage will be modulated because it is operating on a "worst-first" basis--the last chemicals reregistered will be the ones believed most innocuous.

However, the registration program has not yet entered placid waters. The RPAR program is already lagging behind OSPR's virginal plans. Again we find that experience for carbaryl is not unique. The earliest plans were to complete all RPAR reviews by February 1977.¹⁵⁴ In November 1976 the Agency made solemn plans to determine whether RPAR would be issued for 45 problem pesticides by October 1977.¹⁵⁵ At the beginning of July 1977 the number completed is about thirteen, and forty-four still remain in the decision hopper.

Furthermore, the RPAR scheme has not yet proven itself effective at reducing public risk. EPA hopes that the new procedures will either preclude or expedite the public hearings, but registrants still have the statutory right to demand full section 6 proceedings as a last resort to avert cancellation, and it remains conceivable that a logjam of post-RPAR cancellation hearings will yet curtail or even arrest the reregistration program's progress.

What went wrong with the original reregistration program plan? To some extent there must have been management failure. It is difficult to fathom how such naive assumptions about the contents of the pesticide program's own data file could have persisted through the early planning exercises, leaving OPP officials "startled" by reality fully three years after FEPCA was enacted. Slack management, however, could only have endured so long under conditions of political neglect. It may be that legislators, Administrative officials, and EPA leadership were preoccupied by the larger air and water pollution control programs that dominate EPA's budget. Outside observers may have taken excessive comfort in the handful of large and well-publicized cancellation cases and assumed that the pesticide effort was on track. Agency officials may have been distracted by the short-term difficulties of meeting a number of statutory deadlines (many of which accomplishments will lose much of their impact if reregistration is not duly implemented) and may not have recognized the impending reregistration crisis.

Active and timely legislative follow-up would have helped anticipate and/or correct the problem. Oversight, conducted by peripheral committees, came too late to salvage the stated objectives of FEPCA.

B. The Larger Context

There may be a tendency to ascribe the prodigious underachievement of EPA's treatment of problem pesticides to managerial ineptitude. It would be a pity if that were the only inference drawn, for imposition of abler management cannot hope to correct the pesticide situation by itself, and managerial competence alone will not assure success in other regulatory programs analagous to the pesticide effort. The root cause of the continuing pesticides haze is the reign of exaggerated program expectations based on outdated perceptions of the nature of toxic chemicals problem and mistaken assumptions about the ease of solving it.

Public organizations have acted under and fostered a "Delaney Clause" mentality, acting as if all known chronic hazards would be eliminated; a "search-and-destroy" mission is accepted as appropriate. Further scientific information may well prove this strategy hopeless. The proportion of carcinogens among chemicals is now running one of every six tested, and, while inflated by the choice of suspicious chemicals for testing, may be as high as 3-5 percent for the universe of chemicals. Screening studies suggest similar proportions for mutagenicity and teratogenicity--and even this may be the iceberg's tip, as further research may well implicate chemical agents in cardiovascular illnesses, the onset of senility, menopause, mood changes, and many other physiological effects. With further knowledge we may discover the list of "problem" chemicals is enormous, and that few are totally problem-free. The public may have to adjust to this prospect and abandon any expectation of zero-risk regulatory policies.

If the current budget levels accurately reflect our assessment of the importance of toxics, the nation should fashion more realistic goals for regulatory programs. Experience to date in several fields teaches that it is difficult and time-consuming to screen and eliminate chemicals that are already in commerce. Dissatisfaction with regulatory performance in controlling chemical hazards is hardly restricted to the field of pesticides. The identification and regulation of Agency's toxic effluents in EPA's water program has lagged well behind statutory mandates; the Agency's toxic substances program is off to a halting start, despite years of preparation for the new law; standards setting for occupational exposures to chemicals by OSHA and NIOSH is so slow that a GAO official has calculated that "it will take more than a century to establish needed

standards for substances already identified as hazards";¹⁵⁶ and then there is the NCI effort to identify potential human carcinogens.

The Institute's once ambitious screening program has run animal tests on over 200 chemicals but has evaluated and reported them so slowly that FDA's general counsel, among others, has accused NCI of "sitting on" the results.¹⁵⁷ The experience has been so unpleasant that NCI now hopes to terminate its routine bioassay program, leaving it to industry to perform this function.¹⁵⁸

One reason for the disappointing regulatory record is that chemical products tend to have de facto due process rights, despite ambitious attempts to shift burdens of proof to producers. Another problem is that, since it is impossible to prove a negative, agencies find it difficult to clear chemicals from suspect lists, for clearance would be taken as an absolution assurance of safety.

For pesticide regulation, the weakness is not in the language of the statute: FEPCA provides all the safeguards needed to control problem chemicals. The problem is that the law has not been (and, perhaps can not be) implemented--registration files are useless to the point of scandal, tolerances and registration are granted freely without coordination with safety reviews, major cancellation actions are expensive and therefore rare, and the bold plan for reregistration proved a mirage. A clear need is for better Congressional oversight so that the law is not just a forgotten promise. The pesticide program would be far better off, one can argue, if there had not been a total lack of feedback information to Congress in the early years of FEPCA. In retrospect EPA's own biggest mistake may well have been its reluctance to inform Congress that the goal of reregistration was an impossible dream.

NOTES

- 1 This account is indebted to the careful review and amiable criticism of Richard Back of the Union Carbide Corporation and Maureen Hinkle of the Environmental Defense Fund. I hope the final product represents some reward of their patience and gives them identically small quanta of displeasure.
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- 3 Public Law 94-140.
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- 7 Ibid., p. 594.
- 8 FEPCA, sec 3(d) (1).
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- 27 EPA, supra note 17, p. 2.
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EFFLUENT LIMITATIONS UNDER THE FEDERAL
WATER POLLUTION CONTROL ACT

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I. INTRODUCTION

This case study examines the decision-making methods used by EPA to establish effluent limitations guidelines under the Federal Water Pollution Control Act. The guidelines for the beet sugar and dairy industries are used as examples. The effluent limitations guidelines defined minimum levels of water pollution control for the plants in these industries. The decision-making methods used by EPA will be compared to the decision-making methods recommended by the National Academy of Sciences' Committee on Environmental Decision Making² and, to the extent that EPA's methods differed, this paper will attempt to determine why, and whether use of the methods recommended by the Committee would have improved the decision-making process. For the latter purpose, Section V develops an analysis of the beet sugar effluent limitation guidelines that uses EPA data but tries to apply the methods of analysis suggested in Recommendation A, Analysis in Support of Decision Making.

The decision-making methods that this paper will explicitly use as a model are based upon the Committee Report and consist of the following (for detailed discussion see recommendations of the Committee Report,³ indicated in parens):

1. State the objectives of the decision. (A)
2. List the available alternatives. (A)
3. The above statement of objectives and alternatives should be used to guide the data gathering effort. The data should be reviewed by scientists and engineers outside the Agency. (A & C)
4. The data should be related to the alternatives through a listing of the consequences of each alternative. Where feasible and meaningful, these consequences should be expressed quantitatively. (A)
5. The uncertainty should be clearly expressed, preferably in the form of probability intervals. (A & C)

6. Barriers to implementation should be analyzed and considered as part of the decision-making process. (A & B)

7. Where there exist several alternatives, incremental and cost-effectiveness analysis should be done in order to clarify the effects of different alternatives. (A)

8. The data bases, review of the data, the analysis, and the rationale for the particular alternative chosen should be part of the public record. (A, C, & G)

This paper will also emphasize elements of two other recommendations concerning decision-making; the need to establish priorities (K), which will be interpreted here as the application of the above principles to programs as well as individual regulations, and cost effectiveness in achieving environmental objectives (N).

Two techniques were used in trying to determine the extent to which EPA used the above methods: review of the written record, including internal documents generously provided by EPA, and interviews with the principal participants in the decision-making process. Unfortunately, a variety of time constraints meant that the written record does not fully indicate the degree of analysis that was done by EPA. Further, certain key participants in the decision-making process were no longer with EPA and were unavailable for interviews.

II. THE STATUTE

All regulatory statutes provide an initial statement of objectives and the types of alternatives that an agency may consider in meeting those objectives. The Federal Water Pollution Control Act (FWPCA) also set time limits, suggested approaches to guide data gathering, and provided for external review of the standards to be set. This statute presented some of the most serious barriers to adoption of the decision-making methods prescribed in the Committee Report. Severe time limits, though they were not met, still insured that no more than the most cursory attempt could be made to gather new data. Time restrictions also prevented consideration of issues and approaches to standard setting not specifically mandated by the legislation, and, further, prevented careful consideration of the fundamentally new approach to environmental decisions which the Act represented. Because of the originality of the Act, the exact intentions of Congress were inevitably vague and, in some cases, conflicting. This novelty also meant that there was little previous experience or

literature to turn to for guidance. As a result, there was confusion within the Agency as to what objectives and alternatives were appropriate for consideration.

The heart of the law, and the portion which this paper is concerned with, was a three phase program aimed at the elimination of the discharge of pollutants to water in the United States. The first phase was to be completed by 1977 and required at least secondary treatment for all municipal dischargers and at least "best practicable control technology currently available"⁴ (BPT) for all industrial dischargers. The second phase, to be completed by 1983, called for best practicable treatment over the life of the works for all municipal dischargers and at least "best available technology economically achievable"⁵ (BAT) for industrial dischargers. The third phase had no clearly specified requirements, but set a goal of elimination of discharge of pollutants from point sources by 1985. Congress was most confident of the value of the first phase, but expressed doubt about the second phase by calling for a national study commission to make:

a full and complete investigation and study of all of the technological aspects of achieving and all aspects of the total economic, social, and environmental effects of achieving or not achieving the effluent limitations set forth for 1983.⁶

The 1985 goal was even more tentative, because the Act contained no provisions to implement the goal.

The basic instrument for implementing standards on any particular industrial source is the permit. A permit had to be issued to every discharger into navigable waters. The permit would set restrictions "on quantities, rates, and concentrations of chemical, physical, and biological and other constituents."⁷ The permits also specify the data and information that the discharger was required to collect. Though these permits were to be based in part on the technology based guidelines and the guidelines were to be based on the performance levels achieved by given technologies, the discharger was allowed to achieve these limitations with any technology or combination of technologies that he chose.

A problem that almost immediately arose was that these new mechanisms for water pollution control never clearly indicated how BPT and BAT were to be defined for each individual discharger. Section 301 of the Act states that there shall be achieved effluent limitations which require the application of BPT and BAT respectively as defined by the Administrator pursuant to section 304(b). Section 304(b) only calls on the Administrator to "publish...regulations, providing guidelines for effluent

limitations"* (emphasis added). Whether EPA could prescribe minimum national effluent limitations or whether it could only provide ranges for specific applications by individual permit writers remained a serious legal issue until the Supreme Court decided that national effluent limitations were permissible in 1977. Prior to that decision, no two courts had managed to reach precisely the same interpretation of the meaning and relation of the two provisions cited.

The legislation provides EPA with complex instructions as to standard-setting procedures. For best practicable control technology currently available, the legislative history suggests that the intention of both the House and Senate is some "equivalent to secondary treatment for industry,"⁹ although equivalent in what sense is never specified. Both the House and Senate indicated that this definition was not to be considered binding, and the House noted that secondary treatment referred solely to BOD and suspended solids, which may not be the only industrial effluents of concern.¹⁰ Section 304 suggests that in writing guidelines for BPT the Administrator should take into account:

total cost of application of technology in relation to the effluent reduction benefits to be achieved in such application...the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control technologies, process changes, non-water quality environmental impact (including energy requirements), and such other factors as the Administrator deems appropriate.¹¹

Total cost in this context was intended to include economic impact on communities and regions, as well as internal costs. The Senate Report offers the only detailed instructions as to how the Administrator might carry out this task:

The Administrator should establish the range of best practicable levels based on the average of the best existing performance by plants of various sizes, ages, and unit processes within each industrial category.¹²

If all plants in a category have levels of control judged to be inadequate, EPA can require a higher level of control than this average. The law and the legislative history thus offered EPA three possible approaches for defining BPT; equivalent to secondary treatment, average of the best performance, and total cost versus effluent reduction benefits.

Guidance for determining BAT is even more vague. The phrase "economically achievable" is never clearly defined, and the following passage from the Senate Debate on the Conference Report is less than enlightening:

The Administrator will be bound by a test of reasonableness. In this case, the reasonableness of what is "economically achievable" should reflect an evaluation of what needs to be done to move toward the elimination of the discharge of pollutants and what is achievable through the application of available technology--without regard to cost.¹³

With respect to preparing guidelines, the Administrator is to take into account:

age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, the cost of achieving such effluent reduction, non-water quality environmental impact, and such other factors as the Administrator deems appropriate.¹⁴

The change from "total cost" to "cost" can be justified by the exemption procedure designed to prevent plant closings that might lead to major community and regional effects. The Senate report suggests that instead of taking the average of the best plants, as for BPT, the very best performance in each category be used to define BAT.¹⁵ The legislative history also suggests that EPA may consider extensive in-process changes and technologies now only available in pilot form.

To assist EPA in this task and to help insure that independent technical and scientific advice would be brought to bear in formulating the guidelines, Congress provided for an Effluent Standards and Water Quality Information Advisory Committee (ESWQIAC). This Committee was to provide EPA with advice on all guidelines, using information from hearings and other federal agencies to supplement their own knowledge.

All BPT and BAT regulations were to be published within one year of the enactment of the statute. This provided incredibly little time for all data gathering and analysis, particularly if time for comment and review of proposed regulations was to be allowed.

The decision structure set up by the Act bore remarkably little resemblance to conventional professional and academic approaches to decision making concerning water pollution control. An ideal analysis from this viewpoint would be one

which compared the costs of various control measures to how the uses of water were enhanced. Determining the effect on beneficial uses would require establishing, step by step, the effect of the control measures on reducing effluent discharges, the effect of the resulting effluent upon water quality, the effect of water quality upon health and ecology, and finally relating these to various beneficial uses. Because of the enormous difficulties of quantitatively evaluating the benefits of improved water quality, most studies contented themselves with a description of the effects of various levels of water quality, which were compared to the costs associated with the various possible levels of control. A number of studies existed showing general water quality criteria associated with various uses of water ranging from drinking water to fishing.¹⁶ A second major focus was the determination of least cost combinations of controls to achieve a given water quality goal, and, in turn, how the costs were affected by various restrictions.¹⁷ Though many studies limited themselves to controls upon pollution discharge, an increasing number of studies examined alternative management measures such as low flow augmentation, intermittent controls and direct oxygenation of affected bodies of water.

While agreement in any field is seldom complete, certain broad conclusions and policy recommendations emerged from these studies. The cost of water pollution control tends to increase rapidly as the level of control became increasingly stringent. Costs of a given degree of control, whether defined as an absolute level or in terms of percentage reduction, vary greatly both among industries and within the same industry. The effect of discharges on water quality is dependent upon the nature of the body of water and even on the particular location of the discharger on a given body of water. Furthermore, water quality is a result of the combined effect of all dischargers: hence isolated consideration of a single discharger is a poor approach to water pollution control. Several policy recommendations which were commonly drawn from these conclusions are of particular interest here (my summary):

1. Water pollution control programs should be geared to the particular body of water involved. Least cost approaches are most likely to be attained by agencies organized on a river basin basis and able to control all of the sources of water pollution within that basin.

2. Least cost methods of attaining water quality goals require widely different levels of control for different sources: even two otherwise identical sources located at different places on the same body of water might require different levels of control.

3. Elimination of water pollution is exceedingly expensive, would normally result in water quality levels greater than required for any conceivable use, and would generally add to other environmental problems such as air pollution and solid waste disposal.

4. Economists (though not all professionals) strongly endorsed effluent charges as an instrument of control, in part because they lead to least cost methods of control without requiring the pollution control agency to have enormously detailed data on the cost of control for each source involved.¹⁸

The program of technology based standards set up by the FWPCA seemed to violate all of these recommendations. Water quality, one of the basic considerations of any water pollution control program, had been explicitly excluded from the decision-making process. Although costs are listed as a consideration, they seem to be an afterthought and it is not clear how they are to be weighed. The approach of developing standards for particular river basins and for specific locations within a river basin was explicitly rejected as a consideration for technology based standards. The goals of the program were far higher than many would have recommended. The program required that the technology based standards for industrial pollution control be considered in isolation from other sources; and, further, either downgraded or discouraged the use of such alternative approaches as intermittent controls, low flow augmentation or oxygenation. (In fact, the Act did provide for unified water quality planning bodies, but these were to build upon the technology based standards rather than substitute for them.) Effluent charges were rejected outright.

The authors of the legislation were, however, aware of the unusual nature of the program they were establishing and of the criticisms of the academic and professional communities. The Congressional perception of the water pollution control problem was fundamentally quite different from that in the academic literature. The problem, as viewed by Congress, was not one of carefully adjusting control measures to a set of water quality goals; instead they saw the fundamental problem as one of forcing some kind of action to reduce pollution. Past programs seem to produce reams of planning and litigation, but very little action. Goals seemed never to be met; pollution control levels were determined chiefly by what a polluter might be persuaded to agree to. Individual states were reluctant to adopt stringent measures for fear they would lose industry to competing states. In short, there was no pollution control program that was capable of actually providing an assured degree of pollution control. There was widespread agreement in Congress that the benefits of even very stringent degrees of pollution control exceeded the costs.

While the ultimate level of control was subject to debate, there was general agreement that present levels were grossly inadequate.

The recent revival of the permit program from the 1899 Refuse Act seemed to both Congress and EPA to provide an almost ideal instrument for water pollution control. In presenting this bill to his colleagues in the Senate, Senator Muskie approvingly quoted Professor William Rogers on the permit approach:

EPA can exercise a preventive authority it had never before enjoyed. There will be no more prerequisites to action that pollution in one state must cause health hazards in another. No more obligations to prove that the fish kill near the chemical plant actually was caused by the suspected culprit. No more useless two million dollar studies proving that sulfite waste liquor harms oysters.¹⁹

An effluent charge system would also have had some of these advantages; however, such a system was never seriously considered by Congress. The objections to it came from industry, which had no desire for further taxes, and from environmentalists who objected that effluent charges provided a way for an industry to buy its way out of pollution control. Many believed that effluent charges, even if workable, could not produce an easily predictable level of pollution abatement within a given time limit. Finally, the fact that the institutional mechanisms for implementing the permit program were already in place and thought to be well understood was seen to be a significant advantage. Many within EPA viewed the Act as a method of getting on with the permit program they had revived under the 1899 Refuse Act, until their actions had been halted by adverse court decisions on the applicability of the 1899 Refuse Act to pollution control.

Having decided that the permit was to be the basic policy instrument of the nation's water pollution control program, the Congress had to decide how the levels allowed by the permit would be determined. The approach taken was that minimum levels of control for 1977 and 1983 should be determined on the basis of the performances of various pollution control technologies. This approach was based upon four basic assumptions:

1. A program geared to cost effectiveness, whether in terms of water quality or total effluent removal, would require more information than was currently available.
2. Significant periods of time would be required to gather the necessary information, and prepare it in a form

which could stand up to legal examination. The more information Congress required, the greater would be the opportunities for delay through litigation.

3. Standards based on technological performance required little or no information beyond that currently available. Such standards also avoided the need to develop separate analyses of the costs and water quality impact of each individual plant.

4. An optimal pollution control program would require very high levels of control throughout the country, levels beyond secondary treatment or the best performance of any existing plants.

Assumptions 1 and 2 suggest that an ideal program would be accompanied by significant delays. Assumption 3 suggests that there exists an alternative program, which, though not ideal, can be quickly implemented. Assumption 4 suggests that the costs of implementing a less than perfectly cost-effective program will be small, because we can be reasonably confident that the simpler program represents a necessary step toward the ultimate, more ideal program. A number of steps were taken to help determine the nature of the long run program. A study commission was set up to examine the validity of the BAT requirements, the final phase (elimination of discharge) was left non-operative, and a provision was made for developing a water quality based program in those situations where technology based standards alone failed to meet water quality goals. Congress believed that the task of installing the technology-based standards would, in and of itself, result in significant innovations, and provide a far better data base from which to assess both the costs and benefits of further levels of control.

EPA seemed to agree with these basic propositions and the resulting strategy, although it objected to many of the aspects of the Act including the 1983 technology based standards and the goal of elimination of discharge (the House shared these objections sufficiently to insist on a special study commission to examine them). EPA also objected to many of the deadlines in the Act. However, EPA Administrator William Ruckelshaus praised the idea of the BPT technology based standards for the first phase of the program, and did not object to the deadlines established for publishing the effluent limitations guidelines.¹⁹

Congress did not present EPA with a standard decision-making problem because Congress had made major aspects of the decision for itself. Water quality and costs were both among the objectives that Congress considered, but they made a set of initial judgements concerning the tradeoffs between water quality and cost, and between speed and cost-effectiveness of the program. As a result, water quality

and cost effectiveness were not to be major considerations for EPA. One may, of course, disagree with the resulting decision, either on the normative grounds that the value of very high water quality is not sufficient to justify the costs of achieving it, or on the positive grounds that technology based standards could not be easily set with available information and that other more cost effective approaches exist which would have presented no greater implementation problems.

III. ORGANIZATION FOR DECISION MAKING

No understanding of the decision process used by EPA is possible without a realization of the awesome size of the task that lay ahead of them and the severe limitations on time, data, and personnel. Within three years, EPA issued BPT, BAT, and New Source Performance Standards for over 233 subcategories of American industry. The simple statement of these regulations took up 576 pages of the 1975 Code of Federal Regulations. Each regulation had to be documented with information on the nature of the industry, the types of wastes produced, the technologies available for control, and an analysis of the economic impacts of the regulations on the industry. At the start of the task, no organized data base combining this information existed. For many industries, the required data had never been gathered in any form.

At the time of the passage of the Act, the Effluent Guidelines Division (EGD), which would eventually have responsibility for all technical work on the guidelines, employed six to eight people. The Economic Analysis Division (EAD), which was to be responsible for all economic analysis of the guidelines, had only three persons whose primary concern was industrial water pollution control problems. Because of the political sensitivity of the issues involved, the EGD was not permitted extensive preparations or significantly expanded staff, despite the fact that the Senate version of the Act had been published a full year earlier. Some small pilot studies were done prior to the passage of the Act, though they were officially labeled as studies of the old Refuse Act Permit Program.

Both budget and personnel for the tasks were highly limited. The task of developing the effluent limitations was initially budgeted for 15 million dollars, and the actual staff of the division never exceeded 60 people, including temporary summer staff. Problems of personnel were accentuated by the difficulty of obtaining and retaining competent people within the time frame available and a frozen government pay structure. Some competent people left the division, both because of pressure of work

and because the experience gained enabled them to obtain better paying jobs.

A Working Group was set up to guide the development of the effluent limitations for each industry. These groups provided a focus for the enormous range of interests and expertise within EPA that was relevant to the development of the effluent limitations.²¹ The lead role in the Working Group was played by the EGD. The EAD also played a very prominent part in the decision-making process. The roles of the Office of General Counsel, the Permits Division and the Office of Research and Development also deserve special attention.

The head of the Working Group was a member of the EGD staff (normally the Director of the division or one of his immediate deputies). EGD was responsible for all of the technical analysis needed for developing the regulation, and for the drafting of the regulation and the accompanying Federal Register notice. Contract research was viewed as the only possible way to carry out the necessary technical analysis. Though \$15 million was initially allocated for developing effluent guidelines, the EGD never had enough personnel to perform the task in-house. Nevertheless, the goal of the EGD was to use the contractors to augment their own staff.

The EGD tended to view its role as one of insuring adequately stringent guidelines in the face of much opposition. Environmental groups were unable to provide any major input into the guidelines to counter the enormous efforts by industry groups and individual firms. Both the Department of Commerce and the Department of Agriculture consistently supported weaker guidelines. The advisory committee set up by the act (ESWQIAC) also tended to support industry views on individual limitations. Within EPA, the EAD frequently advocated less stringent regulations. As a result the personnel of the EGD came to see themselves as an embattled few, with all of American industry and a significant portion of the federal government opposing them.

The representative from the Economic Analysis Division played many roles; he was directly involved in an economic analysis of the guidelines in question, served as the Office of Planning and Evaluation analyst assigned to the Working Group, and provided the support roles normally assigned under EPA procedures to the Office of Planning and Evaluation. This prominent role for the EAD was the subject of some debate. Some held that economic analysis was unnecessary for developing the regulation and constituted an unnecessary step in a process that required speed. The EAD used contract research for the basic analysis, but lacked the personnel to maintain as close a relationship with the contractors as the Effluent Guidelines Division sought.

The EAD, which provided the internal opposition to the EGD, viewed their role as one of easing transition impacts, while maintaining the strong Congressional desire for high levels of pollution control. This frequently emerged as a concern with plant closings and the problems of smaller facilities.

The permits division was a portion of the Enforcement Office, but consisted largely of engineers. They played an important role in resolving disputes within EPA, because they could serve as a source of data and insights that were being gained from the ongoing permit writing process. The Office of the General Counsel itself played a limited role in the development process. They provided interpretations of the law when that was in dispute, and, at least with respect to the economic analysis, constantly asked "are you sure?" The Office of Research and Development provided representatives to the Working Group and served as a reservoir of expertise. Many of the personnel of the EGD, including its Director during the period examined here, were recruited from the Office of Research and Development.

EPA realized that funds and manpower would be insufficient to complete all of the effluent limitation guidelines within the time frame of the Act. The failure to meet the legislative deadline did not, however, result in extending the length of time spent on any one guideline; limitations were still scheduled to be promulgated within one year of the date on which the initial contract was let. The schedule for producing a guideline may be summarized as follows:

1. Contract let.
2. Six months later--Draft Development Document (the contractor's report) is issued. It is circulated for public comment. The first official meeting of the Working Group is held and the process of revision to produce a proposed regulation begins.
3. Three months later--Initial economic impact study is completed. It is used for final preparation of proposed regulation package, and the proposed regulation is issued. (Note as a result of this timing the proposed regulation can only to a limited degree reflect the results of the economic analysis.)
4. Three months later--Promulgated regulation is issued.

Too often mention of federal government regulation writing summons up an image of hundreds of faceless mediocrities sitting in offices from 9 to 5 turning out page after page of meaningless prose, under the direction of a

highly centralized orderly system of command. This image had little to do with the realities of the preparation of the effluent limitations guidelines. Far from an image of drudgery, I was constantly impressed by the zeal and dedication of those responsible for the effluent limitations. Within EPA, there was a genuine sense of excitement about a new program that might substantially assist in solving a serious national problem. The number of people involved full time in the preparation of the regulations was quite small, and far from feeling like powerful agents of the federal government, they more often felt like a beleaguered few with incredible forces against them. It is certainly the case that industry, together with the Department of Commerce, and the National Commission on Water Quality, employed far more people and funds in criticizing the effluent limitations than were employed by EPA in writing them. Far from being a highly orderly, top down process, the combination of diversity of viewpoints within EPA, dedication to the task, and, perhaps, the fact that those in the working group had separate channels of access to the Administrator, resulted in lively debate and argument on each regulation. No real understanding of the decision process that EPA employed is possible without a constant perception of the tight time schedules, limited budgets and small number of people involved. That the resulting regulations were as good as they were is only the result of long hours and considerable dedication by those responsible for producing them. Further, it is difficult, in a study such as this, to fully capture this process; different interests, viewpoints and considerations were not necessarily the result of a formal structure defining precisely how each consideration would come into play, but rather came out of the debate and the creativity of the individuals involved.

IV. DECISION-MAKING METHCDOLOGY

The proper questions to ask are: "Were these decisions proper within the Congressionally imposed time frame?" and "were the requirements of the Act fulfilled?" Whether or not the promulgated guidelines and standards meet the requirements of the Act was felt to be the minimum requirement of the regulation. (Comment of an EPA official on an earlier version of this case study.)

The time and budget limitations described in the last sections made the development of effluent limitations an awesome task. The task was further complicated by statutory vagueness concerning how the standards were to be set. Whatever the virtues of the general strategy of the Act, remarkably little guidance was given as to how to resolve specific questions. Further, what guidance was offered was

sometimes contradictory. The legislation had set forth three somewhat different criteria to be considered by EPA in establishing BPT limitations: equivalent to secondary treatment, the average of the best plants in the industry, and costs versus effluent reduction benefits. Each of these approaches raised questions of its own, and, collectively, the approaches appeared contradictory.

The suggestion of equivalent to secondary treatment raised the question of how to define secondary treatment. This had to be resolved for the purpose of setting regulations for publicly owned treatment works. For primary treatment there is essentially only one major technique, but secondary treatment as conventionally defined could be any one of four treatment methods which differ with respect to both costs and precise performance characteristics.

After "secondary treatment" is clearly defined, questions concerning the meaning of "equivalent" still remain. Congress was aware that many industries produce wastes for which secondary treatment is irrelevant. For example, most of the water quality problems caused by electroplating operations result from metal ions and cyanide, neither of which secondary treatment systems are designed to act upon. Even in relation to wastes commonly treated by secondary systems, the meaning of "equivalent" presents problems. Because industrial wastes are more concentrated, a secondary treatment system for industrial wastes will remove a greater percentage of wastes at lower costs (per unit of waste or per gallon of water) than a municipal secondary system. If "equivalent to secondary treatment" is defined in terms of percentage removal, then most industries would require less than a secondary treatment system. If this equivalence is defined in terms of how a secondary treatment system would perform on this industrial waste, it implies that industries would have much lower average and incremental costs of removal than municipal systems. If it is defined in terms of equal average or equal incremental costs of removal, many industrial dischargers would have higher percentages of waste removed and tertiary treatment systems. Finally, the suggested approach of "equivalent to secondary treatment" leaves open the problem of how to treat in-plant controls.

Limitations based upon the average of the best would at times differ from limitations based upon equivalent to secondary treatment. What happens if the average of the best plants in an industry involves treatment levels clearly above secondary treatment? This is not an academic question; for the dairy industry, it appeared that the "average of the best" might well involve facilities beyond secondary treatment and incremental costs greater than secondary treatment for at least some plants. The average of the best criteria also raise the disturbing implication

that at least some of the plants designated as among the best in the industry would not meet the resulting standard (an average implies some plants below as well as above the average).

The average of the best criteria also poses the problem of what plants should be grouped together and given a common limitation. At what point should it be decided that processes are sufficiently different to merit separate limitations? In many industries, no two plants have exactly the same processes or make products of exactly the same specifications. For example, the products manufactured in the ice cream industry and the wastes produced vary from plant to plant and from day to day. In most situations it is far from obvious how similar the waste problems of any two plants may be.

The suggestion to compare effluent reduction benefits to total costs provides a way to look at alternatives, but without any suggestion as to how to decide the dollar value of effluent reduction benefits, this approach provided no clue as to which alternative to choose.

The guidance for BAT, while less contradictory, offered no suggestions concerning levels of control, except that these limitations be more stringent than BPT. There is even for BAT additional confusion as to objectives, as Congress does not make clear what the phrases "economically achievable" or "costs" are to mean in this context.

A. EPA's Methodology

EPA decided that the guidelines should be used to define the maximum effluent output that any plant in an industry would be allowed, rather than simply give ranges for performance, or rough guidance for writers of permits. Somewhat countering the key role that this decision gave to the guidelines was the decision to proceed to issue permits before the guidelines even reached draft form. EPA's legal opinion was the "the permit...defined BPT for the facility."²² Thus, large numbers of permits were written with no relation even to the draft guidelines, and still more were written based upon draft and proposed, rather than promulgated, guidelines.

Approximately three months after the Act was passed EPA developed the following approach for performing the basic analysis that was necessary for selling effluent limitations (my summary):

1. Subcategorize the industry on the basis of whether separate limitations will be required.

2. Analyze the waste that the industry produces and decide what effluents should be controlled.

3. Examine the actual effluents of the best performers in the industry. BPT was to be based on the average of the best performers in the industry, while BAT was to be based on the performance of the best single plant in the industry. If the performance of the dischargers was considered inadequate for either BPT or BAT, pilot systems and the technologies used in other industries could be considered. A much stronger proof of availability was required for BPT than for BAT.

4. Examine factors within a subcategory that might call for special consideration such as climate and age.

5. If sufficient data were available, the performance would be derived in two steps: an average for 30 consecutive days based upon 1 year record of performance, and a daily maximum based upon (and oddly this seemed to vary) a level within which the plant could perform from 95 to 99 percent of the time.

6. Choose a production parameter and measure the performance of the best plants in terms of the ration of pollutant to the production parameter. An effluent limitation would then be written requiring that all plants in a subcategory meet this same ratio. Thus a typical effluent limitation would take the following form:

	<u>lbs/lb of product</u> <u>30 day average</u>	<u>lbs/lb of product</u> <u>daily maximum</u>
BOD	3	7
SS	2	5
TDS	3	10

7. Collect several additional types of data on the following subjects. (Each of these seemed called for by specific provisions of the Act, but there seemed to be no clear concept within EPA of exactly how to use this additional information for standard setting.):

a. a clear specification of what technology(s) could achieve the recommended effluent limitation guideline;

b. the costs of that technology;

c. economic analysis of the price, output, employment, plant closing, and investment impacts of the proposed effluent limitation guidelines;

- d. energy requirements of the proposed control system; and
- e. non water quality environmental impacts of the regulation.

This approach is my own outline of EPA's methodology, distilled from examinations of EPA's Request for Proposals, discussions with EPA personnel, and examinations of draft recommendations. It is most relevant to the first stage of the standard setting procedure. EPA's approach seems to have been an attempt to carry out the instructions of the Act concerning factors to be considered. The basic argument for EPA's approach was that it fit the requirements and the legislative intent of the Act. A point should be made about the use of the miscellaneous factors cited in item 7. EPA realized that almost all comments would come from industry and would point out information suggesting a less stringent guideline. By using the rather stringent average of the best criteria in the first draft, EPA hoped to elicit the maximum of information from industry. (As one EPA official pointed out, "The alternative approaches--testing less stringent limits--would reveal little since industry would remain mute and environmental groups lacked resources and knowledge to effectively challenge the outcome."²³)

This methodology relies heavily on the average of the best approach suggested in the legislative history of the Act, and shares its weaknesses. The approach calls for decisions about four separate issues: production parameter, pollutants to be controlled, subcategorization (used here to mean any decision concerning whether separate effluent limitations are warranted for different portions of the industry), and level of control.

The methodology as outlined seriously addresses only the fourth issue, leaving the contractors and the working groups to select the criteria relevant to the other decisions. The methodology seemed designed to gather the necessary data but provided little insight into how to use the data for resolving the issues.

B. The ESWQIAC Methodology

ESWQIAC developed an alternative approach to the process of guideline setting. The method they proposed for subcategorization was to be based on four types of "constraints on standards of performance...treatment technology, operational characteristics, economic equity, and geographical and climatic consideration."²⁴ Subcategories were to be developed as follows:

1. Develop statistical plots of raw waste load and flow for an industrial category. Determine if size, age, or type of process has a major effect and if so break the statistical plots accordingly. Eliminate plants which have extensive water reuse or product recovery not normally practiced in the industry. Base line flow/unit production is one standard deviation from the mean.

2. Determine from waste water treatment operating data on best practical technology if the waste water characteristics have an effect on process performance under optimal design operation conditions. If so, categories should be established with appropriate effluent qualities.

3. Define operating characteristics of the industry. Establish effluent qualities for each grouping.

4. Delineate geographical and climatic effects. Best practicable technology in some cases can be defined by area if spray irrigation or evaporation ponds are applicable. However, in all cases an alternative for discharge using waste water treatment should be considered because land availability or cost could mitigate against land disposal. Waste water characteristics, particularly temperature, should be considered.

5. For each of the groupings defined in 1, the cost of compliance/unit production should be generated. Best practicable technology is defined, and costs are computed by selecting the large plants with prevalent technology. Processes are selected and effluent quality defined for each grouping is considered a reasonable cost equity.

6. As additional data is compiled, it would be added to the data base for current best practicable technology. Treatment models would be updated as the state-of-the-art advances.²⁵

Within a subcategory the level of control was to be set as follows:

1. The raw waste load and waste water flows per unit of production for a subcategory is established statistically on the data base. One standard deviation of the industry-wide waste water flows is used for computation. Plants with water use in excess of this limit are expected to attain this amount by in-plant conservation practices.

2. Best practicable technology for a subcategory is selected.

3. The average effluent quality attainable is determined from process models reflecting present exemplary performance.

4. The average effluent limitation in pounds of pollutant per unit of production is the product of 1 and 3.

5. Effluent variability is defined by considering process operating temperature, variation in raw waste load, and variation in product mix.²⁶

The vagueness in the description of how to develop guidelines reflects several problems in the matrix approach. In March, 1974, I spent a day with the personnel of Vanderbilt Center for Industrial Water Quality Management discussing the matrix approach and their problems in applying it. One problem lay in deciding what constituted a "major effect" for purposes of subcategorization; the statistical plots frequently did not yield simple break points, even where there seemed to be an obvious effect of some type.

A second problem was that of trying to discriminate the effects on raw waste load or performance of five or six variables while only having nine or ten data points with which to work. Perhaps because of this problem, ESWQIAC recommended to Congress that an outline of the matrix method be published and called the guideline required by the Act, and that one year then be allowed for collection of monitoring data on raw wastes and treatment plant performance.

Determining what constituted economic equity was a third problem. The definition arrived at was one of equalizing cost per unit of product, but the people I talked to at Vanderbilt were uneasy about this. If the definition were applied fully, costs per unit of removal, marginal cost per unit of removal, and removal percentages would each differ widely. The resulting rule clearly did not fit an efficiency standard (which might be based upon equal marginal cost of removal) nor would it necessarily prevent plant closings.

The ESWQIAC approach took account of the technology based nature of the standards to be set, but did so by disregarding in-plant controls. The one place that the outline above is highly specific is with respect to determining raw waste loads. The requirement of no greater improvement than that necessary to come within one standard deviation of the industry average overlooks the role of in-plant controls. For example, one of the variables that has consistently been found to affect water use (and to a lesser extent, waste load) is the cost of treatment, either in the form of fees for the use of a combined system or implicitly in the form of operating expenses of the plant's own treatment system. Thus, one of the effects of building a treatment system is almost certain to be a reduction in water use. Similarly, an industry-wide average of water use

will reflect the degree of treatment already in place. A guideline based upon the ESWQIAC system will thus not reflect the degree of control a plant is likely to attain.

In spite of these problems, however, the ESWQIAC methodology was somewhat more specific than that of EPA in that it contained some guidance for establishing subcategories as well as for levels of control. However, some members of ESWQIAC treated this mild improvement in formality as something far greater than it was. Thus it is referred to by Martha Sager, Chairman of ESWQIAC, in her Congressional testimony as a "quantitative, mathematical methodology" in contrast to EPA's "descriptive and qualitative approach."²⁷ EPA remained rightly skeptical of this claim, and similar claims that the method would make it possible to simply load data in a computer and grind out effluent limitations.²⁸ At least one member of ESWQIAC pointed out to me at some length that there never was such a system, and disassociated himself from the Committee's efforts, noting that there had never been a formal vote on these recommendations.

C. Methodology Based upon the CEDM Decision-Making Methods

This section tries to adapt the decision-making methods outlined in the introduction to the effluent limitations decision. The first step in this exercise is to define what objectives are to be considered. The law itself presents three basic classes of objectives to be considered; reduction in effluents, costs and economic feasibility, and non-water-quality environmental impacts. The reduction of effluents is mentioned for BPT as "effluent reduction benefits" and for BAT as "progress toward the elimination of discharge." Either can be measured by the difference between future effluent production by an industry and current levels. Costs clearly include direct expenditures for installing and operating pollution control technology. The references to total costs and economic achievability suggest that more indirect measures of the impacts of regulations, such as plant closures, effect upon economic growth, and unemployment, should also be accounted for. The third category depends upon the particular industry but could include such items as solid waste or air pollution created as a result of removing effluents from the water.

The problem of determining what pollutants should be controlled will not be considered here. Even excluding this decision the range of possible alternatives is vast; however, a sense of equity, and the Act's suggestions somewhat limit the possibilities. Further, it may be more important initially to be aware of the potential range of alternatives, including both level of control and degree of

subcategorization than to unduly limit them early in the decision process. Cost effectiveness can help serve as a guide in selecting alternatives for more detailed examination by determining the least cost ways of getting various degrees of removal of some major pollutant. These least cost alternatives should not be the only alternatives considered, but they can aid in providing a reference point for examining other alternatives.

Because the effluent limitations require a series of decisions for different industries, some overall sense of priorities should be established to answer such questions as what degree of stringency should be required for different industries. A simple first step would be to establish a set of commonly defined quantitative measures of the objectives in question, so that comparison of different industries is possible. This would include common definitions of the general terms "costs" and "effluent reduction." Common definitions and comparability do not in themselves establish priorities, however, they make it possible to answer meaningful questions about priorities. A large variety of approaches could be imagined, depending in part upon one's interpretation of the Act. A rough approach would be based on insuring cost effectiveness among effluent limitations. This could be done by arranging the various component technologies involved by their cost per unit of pollutant removed. All techniques below a given cut-off point (measured in dollars per pound of pollutant removed) would be used, and those above that cut-off point would not be used. (If a technique was below the cut-off point but could only be used in coordination with technologies with costs above the cut-off point, then it would not be used.) The rule could be constrained to insure at least secondary treatment, even if this meant going above the cut-off point. Whether subcategories were necessary could then be decided by whether a significant number of plants were required to use techniques with costs far higher than the cut-off point. Such an approach would insure that for a given level of expenditure one would produce the greatest degree of pollutant removal.

In practice, this system would have to be modified by a number of factors. The possibility of plant closures would have to be considered as a source of costs beyond the direct costs of using various pollution control techniques. Methods would have to be found for accounting for in-plant control methods that could not readily be labeled as technologies (such as "good management").²⁹ One would not want to blindly follow a cost-effectiveness system without modifying the results of such an approach by considering non-water-quality objectives, equity, and distributional effects such as plant closings.

This entire approach, however, would have created a number of implementation problems. Insuring comparability of the consequences would have been difficult in EPA's context and time frame. Even if a minimum set of consequences and definitions could have been arrived at, enforcing their consistency in a meaningful way among a variety of contract research firms dealing with different industries possessing different amounts of data would have been extremely difficult. If success were achieved, the quantitative estimation of consequences would inevitably invite outside comparison of different industries, and would tend to force some kind of consistency among limitations, thereby consuming more time. If the general cost-effectiveness approach for defining priorities were used, establishing cut-off points would present problems. One approach for BOD would have been the comparable costs of BOD removal for secondary treatment for municipalities. Thus "equivalent to secondary treatment" would be defined as equivalent in the costs per unit of removal of the most expensive elements in a municipal treatment system. Cost effectiveness between the municipal and industrial point source control programs could then be compared. However, this ignores the problem of how to deal with multiple pollutants, and cases in which secondary treatment is irrelevant to the types of waste being considered. Further, the entire approach is clearly not required by the law, and some would argue, goes against the spirit of the law. The establishment of the cut-off points and their application would raise many potential legal issues that would only serve to delay in issuing limitations.

D. EPA's Choice of Methodologies

On September 28, 1973 ESWQIAC gave a formal presentation of the matrix method for Russell Train. It was, however, never adopted. Two reasons were cited for this decision: the failure of the method to deal adequately with in-plant controls and, more fundamentally, a strongly expressed opinion "there is nothing there." EPA had sponsored research on the matrix method prior to the passage of the Act and R&D had continued to show an interest in it. At the time of this study, there still existed no version of the matrix method that could be readily implemented. One person within EPA who viewed the method somewhat favorably still suggested that it would take far more time than EPA had available to gather the necessary data. This rejection of the matrix method was partially due to the fact that ESWQIAC claimed the method could do more than EPA believed possible.

Several reasons not presented explicitly by EPA may also have influenced the rejection of the ESWQIAC methodology. As noted, the alternative methodology was presented in September, 1973. By this time, EPA had either finished or

was in the middle of the studies that would produce all of the initial set of guidelines. To adopt the ESWQIAC methodology at this point would have meant abandoning both any chance of meeting the Act's deadlines for even a portion of industries, and almost \$4 million of contractual effort. To adopt it for future guidelines would raise legal and equity questions of a very serious nature.

The ESWQIAC approach required enormous amounts of data. EPA could not gather this type of data in the short-term studies they had planned. The usual approach in EPA studies was to rely on existing data on waste loads and industry performance. The typical study would do some sampling in order to provide a check on the validity of data gathered by industry. Even in those cases, such as dairies, where there was little industry data, the most the EPA contractor could do was gather 30 days of performance data at a small number of plants.

Another problem with implementing the ESWQIAC approach would have been the nature and abilities of the firms that were performing the technical analyses for EPA. EPA had selected as contractors either design engineering firms or the environmental divisions of management consulting firms, the bulk of whose normal business consisted of design work for the industry in question. As a rule, the majority of the staff on these contracts were sanitary engineers. This selection of contractors, under the best of circumstances, provided personnel with extensive experience in the industry and an intimate knowledge of how waste treatment problems could be solved. However, the resulting personnel did not necessarily have all of the attributes one would desire for writing effluent guidelines. They had experience in handling the wastes of individual plants, not with the problems of how to make generalizations about sets of plants. Most practicing sanitary engineers had little experience with statistical methods, and particularly with the application of such methods to large numbers of distinct plants. Their background in operations research, decision analysis, economics, or any other field with an emphasis upon decision-making methods was also limited. Thus, although the ESWQIAC methodology was designed by sanitary engineers, and in part reflects this in its cavalier treatment of in-plant controls, its implementation was probably beyond the abilities of the typical EPA contractor.

The approach outlined here emphasizing explicit analysis and cost effectiveness was never seriously considered by EPA. However, the basic concepts with respect to defining objectives clearly, listing alternatives, and quantitative treatment of consequences were well known to the Agency. The use of a cut-off point to insure cost effectiveness is a concept well understood at least by people in the Office of Planning and Evaluation (which includes the Economic

Analysis Division). EPA's own procedures call for an Administrator's Briefing Package that lists various types of consequences, a discussion of the alternatives rejected, and the reasons for rejection. These procedures, however, result in relatively informal treatment of these issues, and fail to provide assurance of comparable discussions of consequences. This failure to assure comparability was at least, in part, the result of the speed of the effort and the diversity of contractors involved. Even minimal efforts to establish consistency among contracts frequently failed. Some consistency was provided by consistency in the personnel who regularly met to deal with the different effluent limitations. More recently, EPA has made efforts to provide consistent and clearly documented studies of costs across all industries.

Consistency did not seem very important because cost effectiveness was never viewed as a primary concern in implementing the legislation. Only a tenuous argument could suggest that cost effectiveness was a part of the legislative intent, and given the time pressures involved, it was clearly one consideration that could be dispensed with. An attempt to insure cost effectiveness was thought to require more time, effort, and data than were available. Extensive early planning or simultaneous development were seen as a necessity of such an approach. This approach would raise problems concerning how to handle industries with a multitude of pollutants that could be reduced by a single treatment system. To extend a legally mandated time frame in order to meet a condition not required by law seemed out of the question. EPA believed it could consider cost-effectiveness issues by examining economic impacts, which were clearly within the framework of the legislation, without resorting to the formality of cost-effectiveness analysis.

EPA's methodology was successful within the narrow goals EPA had set for it. On the whole the courts have fairly consistently approved EPA's approach and methodology. Limitations have been remanded chiefly due to technical issues such as errors in technical analysis or availability of a technology within the time frame suggested. However, the burden is upon opponents of the methodology to prove it is not consistent with the legislation: to demonstrate other approaches exist which might be more effective is insufficient for striking down the methodology.

V. DATA GATHERING

This section examines the types of data gathered by EPA, the sources for this data, and the ways in which the data was reviewed. The next two sections are concerned with analysis, defined here as how the data were assembled and

used for the purpose of selecting limitations. This distinction is easier to make in this case than in many as the typical document contains a mass of facts about various aspects of the industry, followed by an assembly of those facts for the purpose of proposing recommendations. It is thus relatively easy to see what data were gathered, as against what data were explicitly used, to aid in choosing among alternatives. The two industries examined here, beet sugar and dairies, were chosen in cooperation with EPA; one of the selection criteria was that the limitation for these industries should not currently be in litigation.

A. The Preparation of Technical Data

Four areas of technical information essential to the approach adopted by EPA are:

1. the raw waste loads of the industry and the sources of variance in them;
2. the costs of changing the raw-waste load;
3. the performance of various end-of-process technologies and the sources of variance in performance;
4. the costs of various end-of-process technologies and the source of variance in these costs.

This section examines the extent to which the technical analysis provides support data for the regulation in each of these four areas.

1. The Beet Sugar Industry

The beet sugar industry is a relatively small, homogeneous industry. The industry contains a total of 52 plants in the United States, all of which use essentially the same processes to convert sugar beets to refined sugar. Both the basic inputs and outputs show little variation from plant to plant. Virtually the only significant process or product differences involve whether the Steffans process is used for increased sugar recovery from molasses, and whether adequate markets exist for certain by-products such as dried pulp. The industry practices high levels of pollution control and over 23 percent of the plants have no discharge of water pollutants. These high levels of control are achieved through recycling the major water streams rather than through conventional secondary waste treatment processes. Indeed, because of the nature of the waste, and particularly due to the short lengths of time that the beet

and cost effectiveness were not to be major considerations for EPA. One may, of course, disagree with the resulting decision, either on the normative grounds that the value of very high water quality is not sufficient to justify the costs of achieving it, or on the positive grounds that technology based standards could not be easily set with available information and that other more cost effective approaches exist which would have presented no greater implementation problems.

III. ORGANIZATION FOR DECISION MAKING

No understanding of the decision process used by EPA is possible without a realization of the awesome size of the task that lay ahead of them and the severe limitations on time, data, and personnel. Within three years, EPA issued BPT, BAT, and New Source Performance Standards for over 233 subcategories of American industry. The simple statement of these regulations took up 576 pages of the 1975 Code of Federal Regulations. Each regulation had to be documented with information on the nature of the industry, the types of wastes produced, the technologies available for control, and an analysis of the economic impacts of the regulations on the industry. At the start of the task, no organized data base combining this information existed. For many industries, the required data had never been gathered in any form.

At the time of the passage of the Act, the Effluent Guidelines Division (EGD), which would eventually have responsibility for all technical work on the guidelines, employed six to eight people. The Economic Analysis Division (EAD), which was to be responsible for all economic analysis of the guidelines, had only three persons whose primary concern was industrial water pollution control problems. Because of the political sensitivity of the issues involved, the EGD was not permitted extensive preparations or significantly expanded staff, despite the fact that the Senate version of the Act had been published a full year earlier. Some small pilot studies were done prior to the passage of the Act, though they were officially labeled as studies of the old Refuse Act Permit Program.

Both budget and personnel for the tasks were highly limited. The task of developing the effluent limitations was initially budgeted for 15 million dollars, and the actual staff of the division never exceeded 60 people, including temporary summer staff. Problems of personnel were accentuated by the difficulty of obtaining and retaining competent people within the time frame available and a frozen government pay structure. Some competent people left the division, both because of pressure of work

and because the experience gained enabled them to obtain better paying jobs.

A Working Group was set up to guide the development of the effluent limitations for each industry. These groups provided a focus for the enormous range of interests and expertise within EPA that was relevant to the development of the effluent limitations.²¹ The lead role in the Working Group was played by the EGD. The EAD also played a very prominent part in the decision-making process. The roles of the Office of General Counsel, the Permits Division and the Office of Research and Development also deserve special attention.

The head of the Working Group was a member of the EGD staff (normally the Director of the division or one of his immediate deputies). EGD was responsible for all of the technical analysis needed for developing the regulation, and for the drafting of the regulation and the accompanying Federal Register notice. Contract research was viewed as the only possible way to carry out the necessary technical analysis. Though \$15 million was initially allocated for developing effluent guidelines, the EGD never had enough personnel to perform the task in-house. Nevertheless, the goal of the EGD was to use the contractors to augment their own staff.

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The representative from the Economic Analysis Division played many roles; he was directly involved in an economic analysis of the guidelines in question, served as the Office of Planning and Evaluation analyst assigned to the Working Group, and provided the support roles normally assigned under EPA procedures to the Office of Planning and Evaluation. This prominent role for the EAD was the subject of some debate. Some held that economic analysis was unnecessary for developing the regulation and constituted an unnecessary step in a process that required speed. The EAD used contract research for the basic analysis, but lacked the personnel to maintain as close a relationship with the contractors as the Effluent Guidelines Division sought.

sugar plant is in actual operation (termed the campaign), conventional waste treatment has never been found effective on beet sugar wastes in the United States.

Control of pollution centers around three basic uses of water within the plant: flume and washer water, lime slurry water, and barometric condenser water. Flume and beet washer water is the water used for conveying the beets to the plant and washing them. The usual method of treating this stream is to screen, settle, and recycle it. Lime slurry water has the lime mud extracted which is normally then placed in a holding pond, and allowed to dry out during the off season. The resulting lime mud has occasionally been sold as a by-product but is normally used to reinforce the dike in the pond for the next campaign. Barometric condenser water can be cooled and recycled, with the blow down (the necessary diversion to prevent buildup of solids) recycled to other uses that do not require as pure an intake water. All plants now practice impoundment of the highly noxious lime mud slurries, some degree of recycling of flume water, and most plants at least partially recycle barometric condenser water.

In order to gain a better idea of the problems involved in setting a guideline, EPA chose to prepare the beet sugar and insulation fiberglass industry guidelines within the Agency rather than through the usual contract research process. These two industries were to be used as prototypes for the other effluent guidelines, and were the first guidelines to be issued. These industries were selected because of their apparent simplicity and because the Agency possessed expertise in these two areas.

The first step in preparing the guidelines was to determine the flows and associated wastes for each of the major waste streams in a beet sugar plant. This information was not obtained through analysis of present plants, although such analysis was performed for most other guidelines. Instead the basic source of data seems to have been a 1950 Public Health Service study of the industry. These data were viewed as basically accurate in the light of more recent studies. The water use data were apparently obtained from several plants, though no indication of the precise number is given. The phrase used to describe the results is "typical" rather than a term with precise statistical meaning. The waste load data are based upon a study of an entire campaign of two beet sugar plants. In 1965, ten plants in Colorado, were studied a shorter period of time. Results of this study suggested to Kneese and Lof that "some plants may consistently generate more BCD and suspended solids...and that all plants from time to time will generate substantially higher waste quantities because of process upsets, deteriorated beets, climate conditions during harvest, and other factors."³⁰

Unfortunately no more detailed check upon EPA waste load data is available. Table 1 compares EPA cited water use for a typical plant with other sources of water use data for this industry. While water use is not a direct measure of waste loading, it can have a major effect on the costs of the control measures noted above. Column 1 gives the water use data as reported by the EPA development document. It is identical to the value in the US Public Health Service's study for a typical plant except that EPA's process water figure is based upon a process the original Public Health Service Report chose not to call "typical." The range of values is from the same Public Health Service report and is not reported by EPA, though reasons why water flows might vary are cited in the EPA text, sometimes accompanied by numerical ranges. The next two columns give the values for the beet sugar industry's gross water use as reported by Kneese and Lof for the year 1962 in the appendix of their text.³¹ The data for gross water use are based upon all 59 plants then in the industry and data for flume water use are based on 53 plants. This table suggests both that a wide range of values is found in the industry, which is nowhere accounted for explicitly by EPA, and that the average plant in 1962 had much smaller flows to treat than EPA assumed. Thus, far from using the best plants to establish flows, in this case, EPA used as its basic source a plant with flows, and thus costs, above the industry average.

In addition to not carefully delineating ranges or causes of variation in raw-waste load, EPA also provides no data concerning the cost of changing the raw waste load. In Supplement A,³² the discussions of in-plant controls constantly conclude with phrases such as "No accurate cost can be attributed," "the cost...is one of procedure, and improved operation, administration, and maintenance. No reasonable cost for this method of waste reduction can be made."³³ The finding by Kneese and Lof that the presence of a lagoon reduced water use by an average of 1100 gallons per ton of beets sliced suggests that water use can be significantly reduced.³⁴ In general, this failure to adequately consider in-plant control measures and the use of water flow data from a particularly poor plant lead to an overestimate of cost.

EPA considered four levels of control (two of which involved choices of technology with respect to how to achieve the level) in making its decision on what effluent limitation to set. The levels considered were:

1. No waste treatment or control;
2. Control of lime mud but discharge to receiving streams of all other wastes (a minimum now practiced by all plants in the industry);

TABLE 1
WATER USE IN THE BEET SUGAR INDUSTRY (GALS/TON OF BEETS SLICED)

	<u>EPA^a</u>	<u>Range (1950)^b</u>	<u>Industry Average (1962)^c</u>	<u>Standard Deviation (1962)^d</u>
Flume Water	2,600	1,400 - 4,000	2,100	800
Process Water	790			
Lime Mud Slurry	90	50 - 100		
Condenser Water	2,000	1,000 - 2,500		
Steffan Filtrate	120	120 - 200		
TOTAL	5,600	2,900 - 5,400	4,700 ^e	1,500

- a. Source: U.S. EPA, Development Document for Proposed Effluent Limitation Guidelines and New Source Performance Standards: Beet Sugar Segment of the Sugar Processing Point Source Category.
- b. U.S. Public Health Service, "Industrial Waste Guide to the Beet Sugar Industry," December 1950 as quoted in Kneese and Lof, The Economics of Water Utilization in the Beet Sugar Industry, p. 20.
- c. Kneese and Lof, p. 108.
- d. Kneese and Lof, p. 108.
- e. For reasons not clear to me the average total value is sometimes cited as 4100 gallons per ton of beets sliced in the text. I think this is the result of removing outliers.

3. Extensive recycle of flume water without discharge to navigable waters by settling waste through use of a mechanical clarifier or use of a settling pond;

4. Extensive recycle of condenser water without discharge to navigable waters and use of cooling towers, open cooling ponds, or spray ponds. All of the last three levels of control involve the use of holding ponds for mud and blow down water.

The removal levels to be achieved by consecutive application of these technologies are shown in Table 2. No explanation is provided for the difference in the removal levels used in the cost-effectiveness analysis (and ultimately in the effluent limitations) and the removal levels as shown elsewhere in the document.

Only capital costs are given in the Development Document; instructions on how to derive operating costs and annualized costs are provided, but at no point in the text are either the operating costs or the annualized costs presented. The derivation of these costs is somewhat unusual. The beet sugar industry is almost the sole source of data. Given the extensive data available from various sources on the design and costs of such standard pollution abatement equipment as cooling towers, primary clarifiers, and holding ponds this seems somewhat odd. In at least one case it leads to an unusual conclusion: because five plants reported using a 95 foot diameter clarifier, EPA asserted the costs of clarifying are "industry wide, size independent."³⁵ Clarifier size is dependent on flow and suspended solids content, and clarifiers are readily available in larger and smaller sizes.

Within the limits of these cost functions, however, data are provided to distinguish the effects on both capital and operating costs of soil filtration rate, land costs, capacity of the plant and campaign length. No formula is provided for determining the effect on costs of waste loadings or water use levels different from those of EPA's "typical plant."

2. The Dairy Industry

The dairy processing industry contrasts with the beet sugar industry in many respects. It contains over 4,000 plants and the exact total is unknown. They produce hundreds of different products and a plant may produce either a single product or a number of products. Inputs vary significantly; flavorings may be used and the dairy input can range from low fat milk to cream. The bulk of the industry discharges to municipal systems but the exact

TABLE 2

RAW WASTE LOADS IN THE DAIRY INDUSTRY FOR IDENTIFIED PLANTS
(LB BOD PER 1000 LBS MILK EQUIVALENT)

<u>Subcategory</u>	<u>Mean</u>	<u>Range</u>	<u>Number of Observations</u>	<u>Recommended Limitations</u>	
				<u>BPT</u>	<u>BAT</u>
1. Receiving Stations	.46	.3-.7	5	.5	.4
2. Fluid Products	3.21	.3-7.16	6	1.5	.5
3. Cultured Products	-	-	-	2.0	.7
4. Butter	.80	-	1	.8	.3
5. Cottage Cheese	-	-	-	8.0	4.7
6. Natural Cheese	.54	.24-.93	5	.7	.4
7. Ice Cream	6.75	.18-19.6	10	3.0	1.1
8. Ice Cream Mix	.63	-	1	-	-
9. Condensed Milk	2.2	.41-4.00	2	1.0	.5
10. Dry Milk	1.18	.41-2.44	3	1.5	.7
11. Condensed Whey	.43	.24-.88	7	.4	.2
12. Dry Whey	.60	.02-1.16	5	.6	.3

Source: U.S. EPA, Development Document for Proposed Effluent Limitation Guidelines and New Source Performance Standards: Dairy Products Processing Point Source Category, pp. 96, 129, 135.

number of direct dischargers remains unknown. Pollution control has not until recently been an important issue for the industry. Fred Greiner of the Dairy Industry Committee stated that, historically, the main interest in pollution control had been for by-product recovery, rather than for protection of receiving waters. EPA, with industry assistance, was able to locate and measure the performance of only nine plants practicing secondary treatment or better.

For purposes of developing the guidelines, the industry was initially subdivided into 12 subcategories according to the type of product produced. Limitations for multi-product facilities would be constructed from the limitations for individual products. The data base was extremely limited. For some products there existed no raw waste load data for a plant producing only that product. There were only nine plants found by EPA employing secondary treatment, fewer examples of plant performance than there were subcategories, although all product classes represented in some plants. Table 3 shows the subcategories initially chosen, along with data on their raw waste loads, and EPA suggested levels of in-plant control for BPT and BAT. Waste loads within each subcategory show an even more striking range than those of the beet sugar industry. EPA offers no explanation for this range other than degree of in-plant controls and quality of management. It was assumed for purposes of determining costs of control, that any plant could reach the levels shown for in-plant control for BPT and in turn for BAT at no cost whatsoever. The discussion of costs provides costs for various types of in-plant control, and there is even an attempt in the draft document (dropped in subsequent editions) to determine the cost of improved management and housekeeping; however, it is then assumed that product recovery is sufficient to perfectly cancel these costs. The majority of the plants observed by EPA were thus failing to make a sensible investment by product recovery. This is a strong assertion based on little evidence, and was strongly questioned by the industry. A study of the reaction of dairies in municipal systems to sewer charges found that, while water flows declined from 1.8-2.3 percent for every 1 percent increase in water charges, no significant relationship could be found between BOD and suspended solids surcharges and the resulting discharges.³⁶ If the assumption of zero costs for in-plant controls is accurate, there would appear to be some very poorly run dairies around the country. This seems especially odd in view of the relatively high rates of investment in new equipment in recent years.

The performance of nine secondary treatment systems were examined, and found to average 96 percent BOD removal. In contrast to this, the Development Document found from a review of the literature an average percentage reduction of

TABLE 3

COMPARISON OF ALTERNATIVE REGULATIONS TO NO REGULATIONS (RANGES GIVEN IN PARENS)

	<u>BOD removed</u> <u>(millions of lbs per yr.)</u>	<u>Annualized Costs</u> <u>(1000's of dollars)</u>	<u>Plant</u> <u>Closings</u>	<u>Unemployment (full</u> <u>time equivalents lost)</u>
Alternative 1	9.6 (7-12)	1700 (1350-2050)	3.5 (3-4)	210 (180-240)
Alternative 2	11.285 (9-14)	2450 (2025-2875)	4.0 (3-5)	240 (180-300)
Alternative 2'	11.275 (9-14)	2430 (2050-2810)	3.5 (3-4)	210 (180-240)
Alternative 3	13.285 (11-16)	3295 (2800-3800)	5.5 (4-7)	285 (205-365)
Alternative 3'	13.245 (11-16)	3050 (2600-3500)	3.5 (3-4)	210 (180-240)
Alternative 4	15.0 (12-18)	4300 (3500-5100)	6.5 (5-8)	345 (265-425)

only 92 percent for 97 plants. No explanation was offered for this difference beyond the assumption that the identified plants were "well operated" and the others were not. However, the tests on the identified plants all took place during the summer; and climate can affect biological treatment systems. The average for suspended solid removal in the identified plants was 86.6 percent and showed a very high range of performance.³⁷ No explanation was offered for this range.

In developing costs of end-of-pipe treatment, it was assumed, as noted, that raw-waste loads could be reduced costlessly. From there three further levels of control were examined:

1. 90 percent BOD removal through secondary treatment;
2. 96 percent BOD removal through secondary treatment and sand filtration;
3. No discharge through complete recycling.

In evaluating the costs within the industry and their variations, conservative assumptions were made about technological performance. The 90 percent level of control was assumed to be met by an activated sludge system, the most expensive option for most cases. The 96 percent removal level was met through activated sludge plus sand filtration. The evaluation assumed present average rate of waste-water use per unit of input. (Note that the study of dairy reactions to municipal charges suggests the opposite conclusions from those used by EPA; major water reduction possibilities but low BOD and SS reduction from in-plant controls.) The one variable examined as explicitly affecting costs within a subcategory was the size of the plant. Cost per pound of BOD removed varied by a factor as great as 10 from the smallest plants examined to the largest. The cost data are apparently based upon standard engineering cost curves for an activated sludge facility. Sources of variance not explicitly examined are climate and the use of less expensive treatment system. Variance in terms of the performance of the system could be implicitly determined by deleting the costs of sand filtration.

With respect to the four criteria cited at the beginning of this section for technical data, the data gathering for the dairy processing industry was better in some respects than that for the beet sugar industry. At least an attempt was made to show variation in raw-waste loads. This virtue is mitigated by the assumption that prescribed levels of control can be achieved without cost. A better attempt to show variations in the performance of end-of-process technologies was made for the dairy industry. However,

beyond the examination of the effect of plant size, there is little attempt to bring out the reasons for this range in variation or its effect upon costs of control. There is also no attempt in the initial studies to examine the costs of any alternative less stringent than a well operated secondary treatment system.

B. Economic Impacts

1. The Methodology

The basic methodology used in these studies had three steps:

1. Select a set of model plants to represent the industry and determine the cost of production in these plants both before and after the imposition of pollution control costs.
2. Determine the change in price resulting from the change in costs of production. (This was usually done judgmentally, the two most common assumptions being no increase in price was possible, or that the least cost plants in the industry would be able to pass on their costs to consumers through price increases.)
3. Given the change in costs and price, determine for each segment the change in profits. From this determine plant closings, change in capacity, and change in output.

This methodology poses a number of problems and its application was tempered with a good deal of judgment. The model plant concept is difficult to apply because accurate data on costs of production are difficult to obtain, particularly on a plant-by-plant basis. Pollution control costs were supplied to the contractor by the Effluent Guidelines Division; the economics contractor on grounds of both accuracy (for example, the land costs were questioned as well as the amount of land called for), and the choice of typical plants.

Given that a major objective of the analysis was to determine the number of plant closings, failure to identify the exceptional factors that might lead to unusually high costs represented a serious deficiency. Model plants must be used with care as a method of predicting the number of plant closings. The approach may lead to characterizing a whole class of plants as either viable or non-viable, but further analysis is necessary on the classes found potentially sensitive to plant closings.

Concerning demand, the ad hoc nature of the price assumptions is critical. However, even if the basic price

assumption is correct, the method used by EPA does not account explicitly for regional and specialty markets. For a homogeneous product such as refined sugar, prices vary by as much as 5 percent regionally. For non-homogeneous products, such as cheese, it is difficult to determine a meaningful measure of price to use on a plant-by-plant basis. Thus the demand faced by a particular plant may have little relation to industry average prices. This is particularly true for small plants which tend to serve regional markets or produce specialty products to order.

Both the Department of Commerce and industry have criticized EPA for failing to analyze effects on investment with any care, and failing to examine the interactive effects of different regulations. EPA responded to this by co-sponsoring with CEQ analyses of the combined effect of various environmental regulations on investment and employment (using input-output analysis), but had not attempted to integrate such studies into analyses of particular regulations. To the extent that avoiding plant closings is a major objective, the failure to look at interactive effects of different regulations could be significant. EPA has recently undertaken a set of studies to examine this issue.

2. Beet Sugar

The beet sugar industry provided the very significant advantage of being a small industry for which it was possible to sample all plants in the industry to resolve key questions. However, study of this industry also had some special complexity; any analysis of price changes for the industry would depend on how pollution control affected the cane sugar industry and upon the future management of the import quota system for the industry. EPA and its contractor assumed that the impact of pollution control on the cane sugar industry would have little competitive effect, and assumed that the Department of Agriculture would not allow sugar prices to rise. (As it turned out, the import quotas were dropped by Congress, but a world wide sugar shortage caused prices of sugar to rise spectacularly. A subsequent collapse, however, has resulted in calls for renewal of quotas which are being considered at the time this paper is being written. Analysis of portions of phase II Cane Sugar took account of both cost changes in beet and phase I cane sugar, and of the changed foreign trade situation.)

A basic goal of this economic analysis was to determine the number of plant closings that would result from alternative effluent limitations. In order to do so, DPRA selected model plants distinguished by size, current level of control, and campaign length. As a second step, a

variety of other factors, including land costs, filtration rates, age, and potential for municipal hook up, were evaluated. This study reviewed the costs presented in the technical analysis and indicated the following deficiencies: lack of buffer acreage for ponds, underestimated dredging costs, aeration for odor problems, and underestimates of land costs. None of these items were explicitly corrected: they were only noted as sources of errors. (Milton David of DPRA noted that they were required to use Development Document formulas and technical data for their analysis.)

In the case of the beet sugar industry the model plant analysis could be used as a guide rather than as a final answer. Once the model plant analysis was completed, each beet sugar plant that needed to make major pollution control investments was further examined with respect to a list of 26 modifying factors; these factors were used to judgmentally alter the basic model plant analysis. Ranges were given for estimated numbers of plant closings. In spite of some problems the beet sugar analysis seems to be by far the most thorough and careful attempt to apply the model plant approach that I have seen.

3. The Dairy Processing Industry

The absence of a sound data base caused even greater problems for the economic impact study than it did for the technical data. The economic impact analysis depended on data about the number of dairies using municipal systems. These data were unavailable, particularly for the smaller dairy processors who were not members of an industry organization. The assumptions that there would be no cost increases for dairies with municipal hookups and that no dairy without a municipal hookup could add one at a cost less than that of building their own treatment system made such data extremely important. Given the widespread increases in municipal charge systems brought about by the Act and the increased federal subsidies for interceptor sewer lines the validity of these assumptions can be questioned. Economic data was also not available for some of the EPA subcategories. Thus, while 12 subcategories had been defined for technical analysis, the economic analysis was only developed for five product types. The data source for the development of costs for the model plants is not clearly given in the economic impact analysis. Although the economic analysis uses three or four size classes to determine differentials in costs, size is the only factor affecting costs that is examined. In all cases the data used are directly from the Development Document. The analysis also adopts the document's assumptions about using activated sludge systems plus sand filtration to achieve BPT levels of control. No analysis is done of the sensitivity of costs or plant closings to other assumptions concerning

the technology employed. Cost of pollution control and present costs are used to derive the price increases necessary to pay for pollution control in each class of plant. The exact derivation of the expected price increase is not presented, but the results can be very closely approximated by multiplying the percentage increase required to maintain profits in large plants by the proportion of larger plants which are estimated not to be a part of municipal systems. Though a simple solution to the problem, this approach is difficult to justify analytically.

The relatively small size of the resulting price increases (the highest being 1.1 percent for butter) led the analysis thereafter to focus on plant closings. This portion of the analysis discovered that, even without pollution control costs, the smallest plants in four of the product classes had negative net present values. This portion of the analysis seemed to be confirmed by the high closure rates for such plants in recent years. The problem was handled by using a simple trend analysis, to extrapolate plant closings in the absence of pollution control and then assuming as a first approximation that all remaining plants in these categories would close for pollution control reasons. This simple approach was modified by two further analytical steps; 1) an attempt was made to ascertain the distribution of profits in plants effected by plant closings, and 2) the closure rate in the remaining plants was lowered by 10 to 20 percent to reflect local market conditions. The results indicated that the Act would force the closing of 573 plants, representing 15.5 percent of all plants in the industry. However, because of the small size of most of these plants total production lost was estimated to be only .8 percent and total employees affected only 3,248 (1.6 percent of industry employment).

This analysis did not, however, suggest what should be done about this issue. Given the basic argument that major portions of the industry were rapidly dying out, it seems reasonable that any significant investment would result in closing large numbers of plants.

C. Review of the Data

EPA realized that their time limitations and limited resources would be less constraining if outside comment were solicited both early in the process and with greater frequency than had been done in the past. These public comment opportunities were an explicit part of EPA's strategy in developing the effluent limitations and many officials of the Agency pointed to this feature of the process with particular pride. Initially, the request for proposal itself was presented to industry groups. When the contract was let, one of the first steps was to meet with

major industry groups to seek their cooperation in providing data and in finding exemplary plants for the industry. The contractor's preliminary report, termed the Draft Development Document, was also made available for public comment. Finally, the usual opportunity to comment on the proposed regulation was offered. Although this high frequency of comment opportunities seemed admirable, ESWQIAC, industry, and other federal agencies all complained that the time provided for comment at these various stages was inadequate, particularly for any detailed technical analysis.

EPA officials believed that the short time was inevitable given the legislative deadlines, and felt that they had in part compensated for this by the openness in early stages of the decision process. Despite EPA's receptivity environmental groups were unable to play an active role in reviewing data, or, indeed, in commenting on individual guidelines in any form. Ron Cuten, then with the Natural Resources Defense Council, stated they simply did not have the staff, legal, technical or administrative, to be able to comment on individual guidelines. He specifically mentioned that their technical support was entirely gratis, and he was reluctant to make use of it except where technical issues seemed critical. NRDC, thus, focused its attention on broad issues of statutory interpretation.

Industry groups, the Department of Commerce and ESWQIAC all provided fairly detailed comments on the data, however. The industrial comments, not surprisingly, supported less stringent guidelines, though this frequently took the form of asking for greater degrees of subcategorization rather than explicitly requesting the lowering of guidelines. In part, because the Act authorized EPA to enter plants and examine effluents, most industrial organizations tried to cooperate with the contractor. Industry may also have preferred that EPA base its guidelines on an intimate understanding of the industry's water pollution problems rather than textbook formulas. Most of industry's comments upon EPA's data centered on the diversity of water pollution control problems in the industry, and, particularly, why certain types or classes of plants could not be expected to meet the limitation, even if they employed the suggested control technology. Reading these comments provides a fascinating education in applied pollution control problems and in the diversity of American industry; however, they are biased in the sense that the points raised are solely those that show why a plant would have difficulties in meeting a given level of control, and never why a plant could meet or easily exceed it. The usefulness of their comments was also limited by a tendency to mention a point that could be a problem, but not provide enough information to determine the seriousness of the problem. For example, the Dairy Industry

Committee commented that EPA had not taken account of the role of sugar, flavorings, and other non-dairy inputs that occur in some plants. Clearly, this could be of considerable importance, but the industry provided no further information as to whether these materials actually became part of the waste stream, or what effect they might have had on removal rates. At least in the two cases examined, industry rarely provided new data that could actually serve to resolve an issue.

The Department of Commerce was viewed by EPA as largely a second conduit for industry opinion, and not as an independent source of comment. In an examination of Department of Commerce comments on several industries, I found virtually no comments that did not lead to the conclusion that EPA had either overestimated the costs of a technology or overestimated its performance. Although the comments may have been biased, they did raise points that were not simply a repetition of industry comments. The Department of Commerce appears to have provided the only detailed comments upon the economic impact studies. Further, they took an interest in issues affecting very small firms which are frequently not represented by industry groups.

ESWQIAC, which Congress established as a source of relatively disinterested expertise, also provided comments upon each guideline. The main sources of these comments were informal workshops with industry and an informal application of the matrix methodology outlined in the previous section. EPA officials noted that they found these industry by industry comments far more helpful than the general discussions of methodology. Unfortunately, some within EPA viewed ESWQIAC as simply a third conduit for industry opinion. This impression was in part due to the fact that some members of ESWQIAC, including its chairman, continued to argue for the methodology long after it was a viable option, thus providing a continuing critique of EPA's entire strategy. Such a critique, if accepted, could only result in delaying the BPT standards beyond 1977. One ESWQIAC member attributed ESWQIAC's behavior to simple political naivete. However, some individual members of ESWQIAC, particularly the group headed by W.W. Eckenfelder of Vanderbilt, frequently provided consulting services and technical support for industries suing EPA, thereby lowering their credibility in the eyes of EPA.

Although many questions were raised about the data base for the beet sugar industry, two questions seemed central. The first was the argument by the industry that EPA had failed to adequately consider differences among plants that made elimination of discharge a virtual impossibility for some plants in the industry. It is not always clear from the comments whether the problem being raised is that EPA's

data base is inaccurate in taking account of differences in local conditions, particularly climate and filtration rate, or that the Agency had failed to adequately consider the significance of the data it did have. The latter point is emphasized in several of the comments, which use EPA's own data to demonstrate the very high costs required for some plants to meet the limitation. The industry also argued that EPA's data were inaccurate, and that plants with low soil filtration rates in humid climates would be incapable of meeting 0 discharge with the suggested technology. These comments did not carefully pursue the question of what was the best level of performance that could be expected from available technology, but instead suggested that EPA should adopt a lower level of technology for such plants.

The second set of questions raised by the industry concerned the non-water quality issues. Three issues were suggested: 1) the large pools required for treatment might cause undesirable fogging in the vicinity of the plants, 2) ground water supplies might be damaged by the technology chosen, and 3) aeration of the lagoons might be necessary to prevent the formation of undesirable odors. The last of these questions would seemed to imply that EPA had underestimated the costs of the required system by not including aeration where necessary. However, the actual expenditures that might be required for needed aeration were not estimated in the comments.

The central issue raised about the data base for the dairy industry was its inadequacy. The second issue raised in the comments was a general skepticism about the degree of in-plant control that could be established and whether such controls were as inexpensive as asserted by EPA. The comments suggested that the economic analysis understated the number of plant closings. However, internal review in EPA of the initial data base later demonstrated that the initial analysis had predicted more plant closings than there were documented dischargers of pollutants in the industry.

Certain questions concerning data received little or no review external to EPA. As noted earlier, virtually all comment was aimed at demonstrating that EPA's data had either overestimated performance or underestimated costs. No comments provided information on the opposite sides of these issues. The external review, also did not use data for comparisons with other industries. In many cases, information about costs or relative performance might have been gained by looking at systems in other industries. Perhaps the greatest gap in the external review in these two cases was the lack of detailed comment on the economic impact data. These were several reasons for this gap. First, ESWQIAC and the industry committees responsible for reviewing EPA data consisted largely of persons with

pollution control or production and engineering backgrounds, who would typically feel somewhat uncomfortable with the type of analysis involved. Second, in many cases, industry felt that the economic impact data tended to strengthen the case they were making, and thus argued only that greater attention to this information was called for. Third, the importance of the economic impact analysis to the decision was probably not well understood by those outside of EPA. Within EPA, economic impacts and the role of EAD were considered a crucial factor in arriving at the final decision in both of these industries. Those outside EPA, and particularly the industry spokesman, were under the impression that this analysis had played a relatively minor role. They were also unaware of the difference of opinion that existed within EPA. These false impressions may reflect a more general problem for outside reviewers. The data base was linked so poorly to the actual analysis and recommended solution that it was difficult for an outsider to determine the kinds of improvements or changes in the data base would have any effect upon the ultimate decision.

VI. A POLICY ANALYSIS OF THE BEET SUGAR EFFLUENT LIMITATIONS

This section attempts to take the data base developed by EPA and present it in the form of policy analysis suggested in Recommendation A of Decision Making at the Environmental Protection Agency. The issues focused upon are levels of control and degree of subcategorization. The pollutants to be controlled are taken as given and there is no analysis of the best production parameter. This section is divided into 2 parts, Part A presents a summary of the analysis as it might appear in the context of an actual decision, and Part B briefly explains how the results were derived from the available data.

A. Summary of the Policy Analysis

1. Statement of Objectives

The objective of this regulation is to set maximum effluent limitations upon existing beet sugar processing plants, considering cost and availability of technology and the goals of elimination of discharge of water pollutants by 1985, and of water quality which provides for the protection and propagation of fish, shellfish, and wildlife, and provides for recreation in and on the water by July 1, 1983. These effluent limitations represent maximums because two other regulatory devices, based upon local ambient water quality and toxic substances may be used to provide more stringent limitations for any given plant. These maximum effluent limitations will be issued in two phases, one for

1977 and one for 1983. The Federal Water Pollution Control Act, which mandates these regulations, provides several suggestions as to the approximate level at which these effluent limitations should be set. The 1977 standard is termed Best Practicable Technology Currently Available and is to be based upon a weighing of effluent reduction benefits versus total costs. The legislative history suggests that this standard is not to consider local ambient water quality conditions, and offers the non-binding suggestion that it be the equivalent of secondary treatment for industry. The 1983 standard is termed Best Available Technology Economically Achievable. This standard is to consider costs and permits individual exemptions for plants unable to remain economically viable in the face of the standard.

Thus the first step in the analysis must be to determine the pollution control technologies available to the industry and the levels of control they achieve. The choice of what level of control to apply is then dependent upon the environmental benefits versus the cost involved. Environmental benefits may be measured in part by their contribution toward elimination of discharge or through the degree of effluent reduction. However, this is only a partial measure and cannot be related directly to fish, shellfish, wildlife or recreation. Ideally, there should be some measures of effects upon these variables. Cost will be measured through the effect upon GNP. This measure does not, however, completely capture the value placed upon certain types of costs; as a result the distribution of the costs, the number of plant closings and unemployment effects are further cost related objectives that will be examined in arriving at a decision. (The quantitative specification of these objectives will be taken up in the section dealing with specification of consequences.)

2. Alternatives

The beet sugar processing industry is a relatively small, homogeneous industry. The industry contains a total of 52 plants all of which use essentially the same process to convert sugar beets to refined sugar. Both the basic inputs and outputs show little variation from plant to plant.

The basic technique for water pollution control in beet sugar processing consists of recycling the water used in the plant, and using filtration ponds to dispose of enough of the waste stream to prevent buildup of pollutants in the recycled water. The levels of control are dependent upon which water uses in the plant are subject to recycling and can be conveniently divided into four possible levels

depending upon which major water uses in the plant were recycled:

Level 1: No controls, BOD output of 11 lbs. per ton of beets processed.

Level 2: Recycling of some process water, BOD output of 5.6 lbs. per tons of beets processed.

Level 3: Level 2 plus recycling of flume water and control of temperature of barometric condenser water. Output of .5 lbs. BOD per ton of beet sugar, .5 lbs. of suspended solids per ton of beet sugar. Temperature controlled, pH between 6-9.

Level 4: 0 discharge (Level 3 plus recycling of barometric condenser water).

The legislation does not require all of the plants in the industry to have the same level of control. The legislation encourages subcategorization and specifically mentions age, processes employed, engineering aspects of the application of various types of control, and costs as reasons for further subcategorization. Six possible alternative regulations were considered:

Alternative 1: All plants at level 3.

Alternative 2: All plants at a minimum of level 3, level 4 for those plants that currently own or control adequate land adjacent to the plant for the necessary pollution control facilities at level 4.

Alternative 2': All plants at a minimum of level 3, level 4 for those plants for which the treatment costs per pound of BOD removed are less than \$.38 per pound of BOD removed (treatment costs per pound of BOD to be computed according to the formula dollars per pound of BOD = $.876/F + 15/L + 36,000/CL$, where F is filtration rate measured in inches per day, L is length of operating season, and C is capacity in tons per day).

Alternative 3: All plants at level 3 unless the capacity of the plant is less than 2300 tons per day or the soil filtration rate is 1/16 of an inch per day or less.

Alternative 3': All plants at a minimum of level 3, level 4 for those plants for which the

treatment costs per pound of BOD removed are less than \$.45 per pound.

Alternative 4: All plants at level 4.

3. Specifications of the Consequences

Before the consequences of the various alternatives can be evaluated, it is necessary to define specific, and where possible, quantitative means of measuring the effect of the available alternatives upon the objectives. Both environmental objectives are quantitatively measured by BOD removal. Total BOD removal is defined as annual BOD removed as a result of a change from the present level of control to that required by regulation, excluding all new plants, changes in capacity in present plants, and plants predicted to close even in the absence of regulation.

BOD removal is a simplified measure of the objective of effluent reduction of BOD, TSS, and any other effluents commonly found in the discharge of the plant. Although level 3 set controls upon pH and temperature as well, and level 4 involves elimination of discharge and hence also any effects of these effluents, they are not explicitly quantified here due to lack of data. BOD removal is, however, a rather poor measure of effects of the regulation upon water quality, and in turn, the effects of water quality on recreation, shellfish or fish. BOD's effect in rivers is upon the dissolved oxygen levels found in receiving streams. The dissolved oxygen level is an important determinant of the type of ecology, including the type of fish in a body of water. When dissolved oxygen levels fall sufficiently low, serious odor problems can occur. Thus the ultimate effects of BOD removal range from ecological and recreational to aesthetic. However, it is virtually impossible to characterize the effects of the BOD removal on receiving streams with the data available in this case. Further, the BOD removal is aggregated across many different sites in different parts of the country. The BOD removal at one site may have no noticeable effect on ambient quality and in another area may have spectacular effects. Certain limited statements can be made, however. Over half of the plants not now achieving level 4 discharge into streams in which the ambient quality currently restricts designated uses of the water. On the average, plants now discharging at level 2 each produce as much BOD per year as would the untreated wastes of a city of over 150,000 persons, and plants now discharging at level 3 each produce as much BOD per year as would the untreated wastes of a community of over 15,000 persons.

The second type of objective to be considered concerns the consequences of the regulation upon GNP. Data are

inadequate to examine possible beneficial effects of environment on GNP. Therefore, effects on GNP will measure only costs of the regulation. The effect on GNP is defined here as the net decreases in economic output for all purposes other than implementing the proposed action. Because in this case, no significant effects are expected on the price or quantity of sugar available to consumers, these net decreases can be measured as the effect on real GNP. For plants that remain operating despite the regulation, these costs can be approximated by the cost of treatment, including both the reduction in the after tax profits of the firm and losses to the government due to lost tax revenue. For plants forced to close, the costs measure the loss of value added in the plant (the sum of wages paid, earnings on capital exclusive of depreciation, and rent on land) minus what these resources could earn in alternative employment (return on salvage value and net working capital, rent on the land for alternative uses, wages of workers finding alternative jobs). In cases where the closure effect is uncertain, the costs are reported as an expected value that takes into account the probability the plant will close. Costs are measured in 1972 constant dollars per year and are annualized using an interest rate of 15 percent. Included as costs are the costs which result from a change from the present level of control to that required by regulation, excluding all new plants or changes in capacity of present plants, and plants predicted to close even in the absence of regulations.

The final set of consequences to be examined are the distribution effects of the regulation. Because of the inadequacy of the data no attempt was made to measure the distribution of environmental improvement. Three measures were used to examine the distribution of costs: costs were designated as between costs to the firms in the industry, costs to the federal government through lost taxes and costs to workers in the plant due to unemployment. Two other groups that may bear some of the costs which were not included in the analysis: state and local governments through lost tax revenues, and, potentially more important, beet sugar farmers. The farmer's loss might take one of two forms: loss of federal subsidies through inability to continue growing sugar beets when a processing plant closes, or alternatively, losses attributed in this analysis to present firms may be incurred by farmers in order to insure the continued existence of a processing plant. Costs of lost subsidies to farmers would be counterbalanced by savings to taxpayers who would no longer have to pay these subsidies.

Two additional distributional measures are presented which are not measured in dollar terms: the number of jobs lost and the number of plant closures. It should be carefully noted that the effect of unemployment and plant

closures on GNP is already accounted for. The measure of unemployment effects is somewhat unusual due to the seasonal nature of the industry. A beet sugar plant has approximately 50 full time employees. It was estimated that almost all of these full time employees have skills that would insure fairly quick reemployment. The typical plant also employs approximately 200 part time employees. Because beet sugar plants are typically located in rural areas or very small communities, it may be very difficult for individuals permanently located in these communities to find other part time jobs. The measure of unemployment used here is the best estimate of the number of part time employees who would not be able to find equivalent part time work. Thus the unemployed noted here probably do not include persons deprived of their primary job or persons who are the primary income earners for their families. Unemployment is measured in full time equivalent jobs lost to the affected areas.

4. Comparison of the Consequences of the Alternatives

Tables 3, 4, 5, and 6 present the quantifiable consequences for each alternative. Table 3 shows the consequences for each alternative as compared to no further pollution control. Table 4 presents an incremental analysis of each alternative, in terms of increasing BOD removal, and the consequences shown are the difference between that alternative and the next less stringent alternative. (Where two alternatives have approximately the same BCD removal, as do 2 and 2', and 3 and 3', the next less stringent alternative is used for comparison.) The ranges indicated in Tables 3 and 4 represent the judgment that the particular variable shown will be within the range 80 percent of the time, below it 10 percent of the time, and above it 10 percent of the time. Tables 5 and 6 show the distribution of the costs as compared to no further regulation and incrementally. The data and analysis used to derive these consequences are given in the next section of this report, and in An Economic Analysis of Effluent Guidelines, The Beet Sugar Industry,³⁸ and Development Document for Effluent Limitation Guidelines and New Source Performance Standards: Beet Sugar Processing.³⁹

Alternative 1 would require the six plants now at level 2 to meet level 3 requirements. The plants are major sources of BOD, being approximately equivalent to a city of 150,000 persons discharging untreated wastes. This alternative would account for 65 percent of the total BOD now produced by the industry. This effect could be achieved at a cost of approximately 1.7 million dollars per year. The cost per pound of BOD removed would be approximately 18 cents a pound. With present data, it is difficult to put this figure in context, but for comparison the incremental

TABLE 4

INCREMENTAL ANALYSIS OF THE ALTERNATIVES (RANGES GIVEN IN PARENS)

	BOD Removed (millions of lbs per yr.)	Annualized Costs (1000's of dollars per yr.)	Cost per lb. of BOD (dollars per lb. removed)	Plant Closings	Unemployment (full time equivalents lost)
Alternative 1	9.6 (7-12)	1700 (1350-2050)	.18	3.5 (3-4)	210 (180-240)
Alternative 2	1.685 (1.4-2)	750 (650-850)	.45	.5 (0-1)	30 (0-60)
Alternative 2'a	1.675 (1.45-1.9)	730 (650-810)	.43	0 (0)	0 (0)
Alternative 3 ^b	2.0 (1.5-2.5)	845 (500-1200)	.42	1.5 (0-3)	75 (0-150)
Alternative 3'b	1.95 (1.65-2.25)	600 (500-900)	.30	-.5 (-1-0)	-30 (-60-0)
Alternative 4 ^c	1.7 (1.45-1.85)	1005 (280-1730)	.62	1.0 (0-2)	60 (0-120)

a. Incremental analyses is measured from alternative 1, as alternative 2' is nearly identical to 2 in BOD removal.

b. Alternative 3 and 3' are measured incrementally from alternative 2, as the two alternatives are nearly identical in BOD removal.

c. Measured incrementally from alternative 3.

TABLE 5

DISTRIBUTION OF COSTS AS COMPARED TO NO REGULATION (\$1000's OF DOLLARS PER YEAR)

	<u>Government</u>	<u>Firm</u>	<u>Workers</u>	<u>Total</u> ^a
Alternative 1	495	485	725	1705
Alternative 2	815	805	830	2450
Alternative 2'	860	850	725	2435
Alternative 3	1165	1050	1080	3295
Alternative 3'	60	1090	800	3050
Alternative 4	1585	1470	1280	4300

a. Not equal to values shown in Table 3 due to rounding errors.

TABLE 6

DISTRIBUTION OF COSTS; INCREMENTAL EFFECTS (\$1000's OF DOLLARS PER YEAR)

	<u>Government</u>	<u>Firm</u>	<u>Workers</u>	<u>Total</u> ^d
Alternative 1	495	485	725	1705
Alternative 2	320	320	105	745
Alternative 2' ^a	360	360	0	720
Alternative 3 ^b	350	245	250	845
Alternative 3' ^b	315	315	-30	600
Alternative 4 ^c	400	400	200	1000

a. Incremental analyses is measured from alternative 1, as alternative 2' is nearly identical to 2 in BOD removal.

b. Alternative 3 and 3' are measured incrementally from alternative 2, as the two alternatives are nearly identical in BOD removal.

c. Measured incrementally from alternative 3.

d. Not equal to values shown in Table 4 due to rounding errors.

cost of BOD removal for going from primacy to secondary treatment is over \$1.00 per pound of BOD for small communities. For the dairy industry, costs of over \$1.00 per pound were considered acceptable in regulations issued by EPA. The distributional effects of this alternative are somewhat unusual. Of the six plants effected, it is estimated that three or four will close. As a result the costs of regulation are relatively concentrated; 30 percent of the costs are borne by firms in the industry and over 40 percent are borne by workers who may be unable to find other part time work. For the workers unable to find other work, these costs amount to an average of \$2,000 per person per year.

Alternative 2 requires an additional nine plants now at level 3 to reach level 4. This discharge from these plants is approximately equal to that of the untreated waste from a community of 15,000 persons. An additional 1.685 million lbs. of BOD would be removed by this alternative. The additional costs of this BOD removal are \$750,000. The cost per pound of BOD removal is approximately \$.45. Because this alternative involves at most one additional plant closing, a smaller share of the costs is borne by the workers, however, the share borne by the firms in the industry increases to over 40 percent.

Alternative 2' has approximately the same costs and BOD removal as Alternative 2 but differs with respect to the types of plants required to move to level 2. Only five plants are required to move to level 2, but they are larger dischargers of BOD than those plants affected by Alternative 2. The consequences also differ with respect to distributional effects, Alternative 2' involves no additional plant closings, and consequently has smaller unemployment effects with none of the additional costs borne by the workers. The formula used to determine the cut-off point is based upon standard engineering cost curves, but may lead to enforcement problems because firms near the cut-off points may question its accuracy in the courts.

Alternative 3, in addition to requiring all plants now at level 0 to reach level 1, also requires 17 plants to go from level 1 to level 2. These 17 plants do not include all of the plants that would have been required to reach level 2 under Alternative 2. Due to the different combination of plants the incremental costs of BOD removal are actually lower than those for Alternative 2. This alternative would cause 1-3 additional plant closures. However, because the plants that close in this case are characterized by relatively short work seasons, the costs borne by workers is smaller and the cost per worker is only \$1000 per year.

Alternative 3' has approximately the same BOD removal as Alternative 3, but does so with a different combination of

plants and at somewhat less cost. The best estimate of cost savings is \$245,000 but the range is large, from costs \$10,000 more to savings of \$500,000. This alternative requires nine plants to move to level 2, as compared to 17 for Alternative 3; thus the plants involved here are much larger dischargers than those considered in Alternative 3. The greatest difference between the two alternatives is in the distributional consequences; Alternative 3' causes fewer plant closings than Alternative 2, while Alternative 3 causes 0 to 3 additional plant closings. As a result a higher proportion of costs are borne by workers in Alternative 3 than in Alternative 3'. The use of the formula in this alternative may lead to enforcement problems.

Alternative 4 requires all plants in the industry to reach level 2, which would result in elimination of discharge of water pollutants from the industry. This goal can be accomplished with an expenditure of an additional 1 million dollars a year. The additional BOD removal is 1.65 million lbs. per year. The incremental cost of BOD removal is still below that for some municipal facilities and for some dairies, but is above that for many municipal facilities and above the cut-off used for some portions of the dairy industry.

5. Sources of Uncertainty and Limitations of the Analysis

Two major sources of uncertainty have not been incorporated into the ranges presented in this analysis. First, it has been assumed throughout that the regulations could be implemented as written. All consequences assume that a plant required to meet a given level of control will, in fact, install and operate the equipment necessary to meet that level of control. (The possibility that in some cases the required equipment may not meet the precise level of control desired or may exceed it has been included in the ranges, however). The second source of uncertainty not accounted for in this analysis concerns government policy with respect to sugar production. At the time of this regulation, this industry's markets were heavily influenced by the U.S. Department of Agriculture through a system of subsidies to farmers and a system of quotas on imports. It was assumed throughout this analysis that this system would be managed so as to keep the prices of sugar approximately constant at 1972 levels. Many of the predicted plant closings and, in turn, some portion of the costs would be altered if the management of the quota system were tightened to allow less foreign sugar into the country. An increase in subsidies to farmers, might also reduce the number of plant closings and transfer some of the burden of the costs to the federal government.

Table 7 indicates the relative importance of different sources of uncertainty in the data for estimates of BOD removal and total costs. It shows the percentage reduction in the ranges given for Alternative 4 if the variable in question was known with certainty, but all other variables remained uncertain. For total costs the most important sources of uncertainty are uncertainty as to whether a plant will close and uncertainty as to how the resulting foregone production will be replaced.⁴⁰ For BOD removal the most important source of uncertainty is uncertainty as to how much BOD will actually be removed by the technologies in question.

B. Preparation of the Policy Analysis

Having outlined the alternatives to be considered and the objectives to be used to compare them, the next step in the analysis would be evaluating the alternatives with respect to these objectives. Given the many sources of variation from plant to plant in both costs and BOD discharge, the small number of plants in the industry, and the availability of a plant by plant data base, it is expedient in this case to perform the necessary analysis plant by plant. Table 8 shows a worksheet for determining the consequences upon one plant, in this case, plant 12, of being required to move up from level 3 to level 4. The first step is to estimate the change in BOD discharge. It was estimated that the effect of such a change is a reduction of .5 pounds of BOD per ton of sugar processed. The second step was to determine the costs of treatment. Costs are divided into three components; depreciable capital, non-depreciable capital (land), and operating and maintenance costs. There are three different treatment elements which contribute to non-depreciable capital: 1) recycling costs estimated as \$61,000 per plant, 2) capital cost of a cooling tower, and 3) the capital cost of the filtration pond. (These costs are based upon standard cost estimating formulas and a review of actual costs incurred by plants that have constructed similar systems, see the Development Document for full discussion.⁴¹) The one major land cost is that of land for the filtration pond. Operating and maintenance costs are estimated as 10 percent of depreciable capital. In order to place these three types of costs on a comparable basis, it is necessary to provide a discounting and depreciation formula; the costs may then be presented as either present value or annualized equivalents. In this case annualized costs were used. The costs were annualized using a discount rate of 15 percent and a depreciation rate of 5 percent.

The price of beet sugar was determined at the time of this analysis by the management of sugar quotas by the Department of Agriculture. It was assumed by EPA that this

TABLE 7
SOURCES OF UNCERTAINTY IN BEET SUGAR ANALYSIS

<u>Variable</u>	<u>Source of Uncertainty</u>	<u>Percentage Reduction in Range of Total Cost if Variable were known with Certainty^a</u>	<u>Percentage Reduction in Range of Total BOD if Variable were known with Certainty^a</u>
Treatment Costs	+20% for each plant	3%	N.A.
Foregone Profits	+20% for each plant	3%	N.A.
Plant Closure	depends on interest rate used	64%	6%
BOD	+40% for each plant	N.A.	82%
Foregone Production	\$.30 per ton of beet production foregone	23%	N.A.

a. Not equal to 100% due to nonlinearities in determining variances. Each percentage reduction assumes that uncertainty remains for all other variables.

TABLE 8

SAMPLE PLANT WORKSHEET

Plant #12

Capacity (c): 3300 tons per day
 Campaign length (L): 125 days
 Filtration rate (F): 1/4 inch per day
 Estimated value of land (v): \$84,000 per acre
 Change in level of control: Level 1 to Level 2
 Number of Employees (E): 200
 Wages per day (w): \$14.40
 Discount rate (r): .15 (.12 used for sensitivity in one set of calculations)
 Depreciation rate (d): .05
 Marginal tax rate (t): .5
 BOD removal: (.5cL) = 210,000 lbs. per year

Cost of Treatment

Depreciable Capital (D):

a. Recycling Equipment: \$61,000
 b. Cooling Tower (56 x c): \$185,000
 c. Filtration Pond $\frac{.0404 \times c \times L}{F}$: \$67,000
 d. Total (a + b + c): \$313,000

Non Depreciable Capital (Land) (N):

(Land) $\frac{.0000202 \times L \times c \times v}{F}$

Operation and Maintenance (O):

(.1 x D):

Total Annualized Costs (A):

(r + d) x D + r x N + O:

Cost to the Firm

(A x t):

Cost to the Government

(A x t):

Value of Remaining Open:

Value to the Firm (F)

(at discount rate of .15)

Earnings

-Return on Salvage Value

-Depreciation on Salvage Value

-Taxes

+Annualized Value of

Tax Write-off

Net

(at discount rate of .12)

\$604,000
 161,000
 107,000
 300,000
 34,000

\$ 70,000 per year

\$ 95,000 per year

Value to the Government (G): (at discount rate of .15)

Taxes Paid Now \$300,000
-Value of Tax Write-Off 34,000
-Taxes on return on Salvage of Value 161,000

Net \$105,000 per year

Value to Employees (V): $(.5W \times E \times L)$ \$178,000 per year

Total Value of Remaining Open $(F + G + V)$: \$353,000 per year

Probability of Closure

Without Regulation: 0

With Regulation: 0

Total Cost

To Government: \$ 57,000 per year

To Firm: \$ 57,000 per year

Total: \$114,000 per year

management would not be affected by either production costs or total U.S. production and that sugar prices would not be affected by any changes in production costs. As a result, treatment costs would come entirely from profits. Given a marginal corporate profits tax of approximately 50 percent, this means that treatment costs would be divided evenly between the firm undertaking these costs and the federal government.

However, the firm need not make these treatment expenditures, it has the alternative of closing the plant instead. In order to determine whether this would happen, it is necessary to examine the value to the firm of remaining open. Estimates of the various elements in the balance sheet of a typical plant were developed in an Economic Analysis of the Beet Sugar Industry.⁴² The value to the firm of the plant remaining open is determined as the before tax earnings, minus the return on the salvage value, minus the depreciation on the salvage value, minus taxes, plus the value of tax write-offs of losses due to differences between book value and salvage value. This value was computed at two private discount rates; 7.5 and 6.0 percent. The probability of closure, following EPA, was determined as 0 if the foregone profits to the firm were greater than 0 at a 7.5 percent discount rate, .5 if the profits were less than 0 at a 7.5 percent discount rate but greater than 0 at a 6 percent discount rate, and 1 if the profits were less than 0 at a 6 percent discount rate. The firm is not the only party that bears costs if the plant is closed. The loss to the government due to foregone taxes is equal to the taxes presently earned minus the taxes it will earn upon returns on the salvage value minus the annualized value of the tax write-offs the firm is able to take upon closing. It was assumed that half of the workers would be unable to find equivalent part time work in calculating losses to workers.

In this case the plant is certain to remain open with or without the regulation. As a result the total costs are simply the treatment costs. If the probability of closure changed from 0 to 1 as a result of the regulation then the value to remaining open would be the costs of the regulation. If the probability of closure changed from 0 to .5, then the costs of the regulation would be half the treatment costs plus half the closure costs. A change in probability of closure from .5 to 1 would be computed as half the value of remaining open.

Once the plants that will be effected by an alternative are known, total BOD removal, costs, number of plant closings and unemployment are determined by adding the values from the individual plant worksheets.

The treatment of uncertainty used in this example is quite simple and easily calculated. Ranges for each variable for each plant were estimated by the analysts.⁴³ In the judgment of the analyst, the value of the variable will be inside the range 80 percent of the time, below it 10 percent of the time, and above it 10 percent of the time and can fall anywhere within the range with equal probability. The variance of the variable can then be determined from standard formulas.⁴⁴ Where individual variables are independent, determining the variances for a given alternative is simply a matter of summing the individual variances. Ranges for totals can then be computed by adding or subtracting the standard deviation times 1.6.⁴⁵ This approach is simple to use but the estimates of uncertainty are rough and no allowance is made for unusual features in the resulting distributions.

Having developed the consequences of the alternatives, it is frequently useful to examine, in the light of the results, whether other alternatives should be considered. In this case, Alternatives 1, 2, and 4 were developed early in the decision process. After studying the results for individual plants, EPA developed Alternative 3 in order to find an alternative with greater BOD removal than Alternative 2 but with less severe economic impact than Alternative 4. Alternatives 2' and 3' were developed to determine if some more cost-effective alternatives existed. In order to determine the absolute cost effectiveness of the alternatives, the plants were arrayed in order of increasing cost of BOD removal. The least cost alternatives for any given level of BOD removal therefore consist of the set of plants with the lowest costs of control. Such an array is shown as Table 9. The next problem was to determine whether there exist simple implementable rules that could come closer to these least cost solutions than Alternatives 2 and 3.

One such rule that incorporated in Alternatives 2' and 3' is a formula that calculates additional cost per pound of BOD removed. In the case of Alternative 3', this approach is very close to the least cost solution, while for Alternative 2' it is not. This is largely because the least cost solution frequently calls for plants with extensive equipment already in place to increase their level of control. Alternatives 2' and 3' were found to have the additional advantage of causing fewer plant closings, and thus 2' was retained for further considerations in spite of having no significant improvement in cost effectiveness.

VII. ANALYSIS AND RESOLUTION OF THE ISSUES

There is no single analysis by EPA in the public record that simply summarizes the alternatives considered, the

Table 9. Cost Effective Levels of Control

Cost (\$/lb. of BOD)	Total BOD Removal (millions of pounds)	Total Cost (thousands of dollars)	Change in Probability of Plant Closure as a result of BOD reduction	Level of Control Required
.088	1.32	116	0	1
.119	1.53	141	0	2
.129	1.89	186	0	2
.166	3.49	453	0-1	1
.173	5.09	730	0-1	1
.189	5.67	836	.5-1	1
.204	8.63	1440	0	1
.214	10.17	1770	0-1	1
.229	10.54	1856	0	2
.252	10.74	1906	0	2
.284	10.97	1970	0	2
.377	11.06	2002	.5-1	2
.403	11.29	2095	0	2
.417	11.48	2170	0	2
.44	11.84	2328	0	2
.486	12.06	2433	0	2
.486	12.28	2540	0	2
.49	12.61	2700	0	2
.515	12.82	2806	.5-1	2
.518	13.22	3013	0	2
.528	12.29	3127	0	2
.53	13.74	3310	0	2
.551	13.95	3398	0	2
.56	14.09	3476	0	2
.567	14.18	3524	.5-1	2
.59	14.31	3601	0	2
.614	14.46	3693	0	2
1.09	14.63	3873	0-.5	2
1.15	14.92	4206	0-.5	2
1.35	14.99	4301	.5-1	2

consequences of each, and the reasons that the selected alternative was considered the best choice. This is in part due to the informality of the decision process, which brought the needed facts and analysis together through meetings and discussions. It is also due to the division of the analysis into two parts: a technical analysis and an economic analysis. Both documents contain material relevant to an analysis of the alternatives, but neither contains all of the relevant material. Finally, the analysis was continuously refined and updated to deal both with points being made by outsiders and points raised in internal discussions. As a result, the earliest of these analyses, (the Draft Development Document), which had a single set of authors, frequently contains the clearest reasoning behind its proposals. As work proceeded from this point, there are increasing problems in determining the precise consequences of, or reasons for, a given alternative.

A. The Beet Sugar Effluent Limitations

Two alternatives were explicitly considered with respect to the production parameter; tons of sugar beets sliced (the basic input to the plant), and pounds of refined sugar produced (the basic output of the plant). The problem is not solely one of convenience, since the amount of sugar produced from a ton of beets varies both within a given season and from year to year. Though much of both the technical and economic analyses that EPA produced were developed in terms of tons of beets sliced, the effluent limitations themselves were issued in terms of pounds of refined sugar produced. Virtually all outside commenters urged EPA to use tons of beets sliced, arguing that this more accurately represented the amount of BOD a plant would produce. EPA argued that although this might be the case for the total waste load of the plant, the only waste load the limitations were concerned with was barometric condensor water, and for this particular stream, sugar production was a better measure than tons of beets sliced. Neither the commenters nor EPA provide sufficient data in the public record to enable an outsider to resolve the issue or even develop a clear opinion about it; persons I spoke with at EPA, however, stated that this question was very closely analyzed.

The only major debate with respect to pollutants controlled was whether temperature should be controlled in those plants that were not required to meet elimination of discharge. Both industry and the Department of Commerce questioned the importance of thermal pollution. The consequences of this choice are not clear from EPA's analysis. A temperature requirement would seem to require some installation of cooling equipment, yet neither the technical nor the economic analysis ever examine the costs

of a level of control which included cycling of condenser water but not elimination of discharge. The only possible explanation available is that it was expected temperature could be controlled by mixing condenser water with cooler water from other sources. This is not, however, clearly stated.

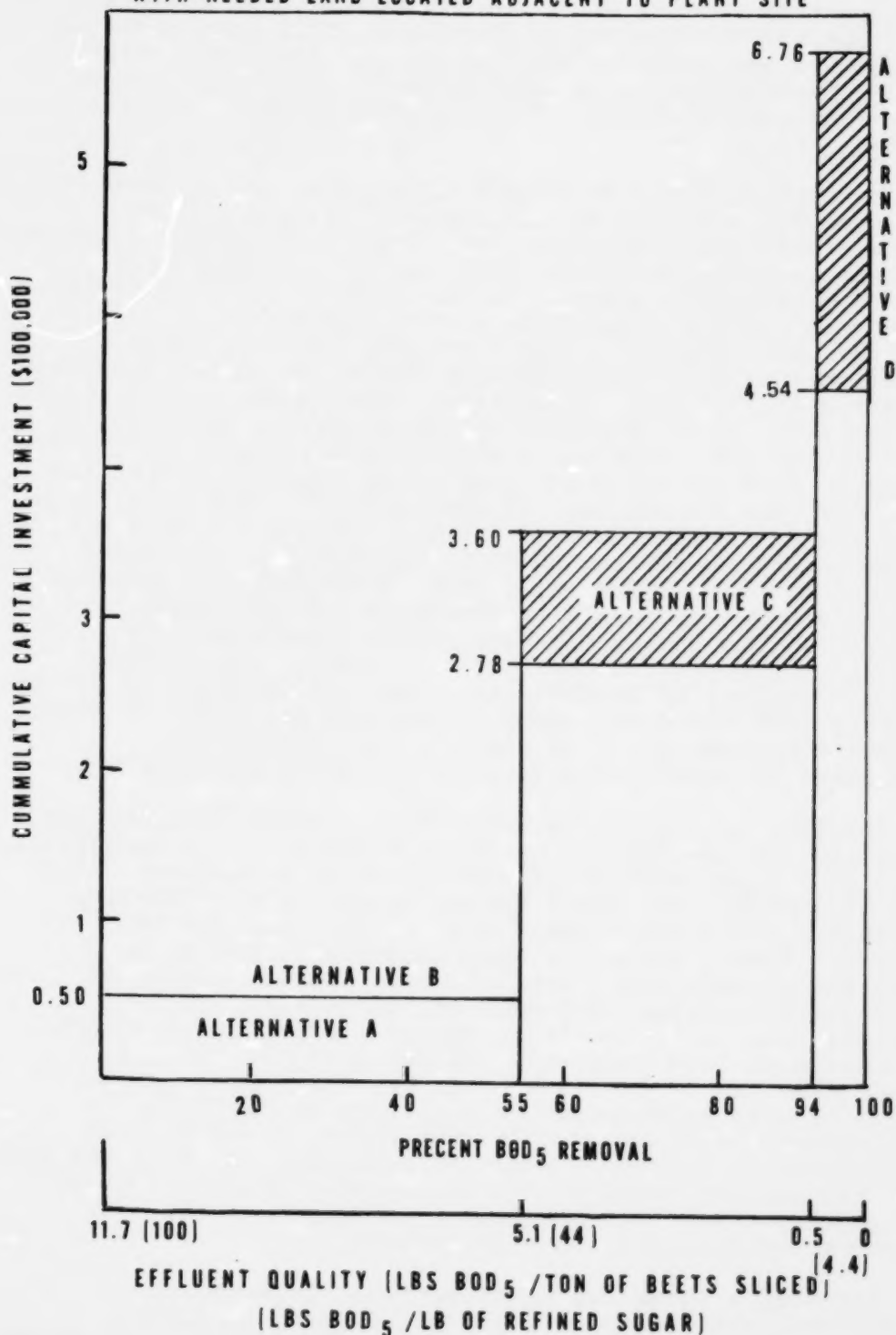
The central focus of debate within EPA, and in most of the comments, centered on the level of control and the degree of subcategorization. The Draft Development Document had presented the necessary data for the analysis of a variety of possible effects on the costs of various levels of control and for developing a wide variety of alternatives. Figures 1 and 2 present the only formal comparisons of cost effectiveness presented in the document and these comparisons are limited. They cover only a single sample plant, whose capacity is approximately the industry average, but the plant has a significantly higher filtration rate than many plants and a much lower campaign length and land cost than are typical of the industry. The only costs presented are capital costs, (though formula for determining operating and annualized costs are provided). The units chosen for the analysis are 1000's of dollars per pound of BOD removed per thousands of pounds of refined sugar capacity. This choice of units poorly represents the economic impact and the cost effectiveness. In terms of economic impact, it ignores the effect of campaign length in lowering both costs per pound of BOD and per pound of sugar. Because costs per pound of BOD are not represented, comparison to other industries is virtually impossible.

Finally, by presenting only capital costs, the figures overemphasize the importance of land costs. If a measure of costs over time, such as present value or annualized costs, were presented, land would appear to have a much smaller influence upon total costs. This is the case for two reasons: first, operating costs are unaffected by land costs and second, other capital costs include a cost of depreciation whereas land does not depreciate. This possible bias in the analysis toward overemphasizing the importance of land costs was reflected in the initial recommendations on levels of control, which were for all plants to meet elimination of discharge by 1977, unless insufficient land was owned by the plant, in which case elimination of discharge would be postponed to 1983, and the 1977 requirement would be for elimination of discharge of all sources other than barometric condenser water. (Alternative 2 in the above analysis.)

Although a large number of economic impacts are considered, the analysis ultimately focused on plant closures as the basic measure of economic impact. EPA chose this measure because:

FIGURE 1

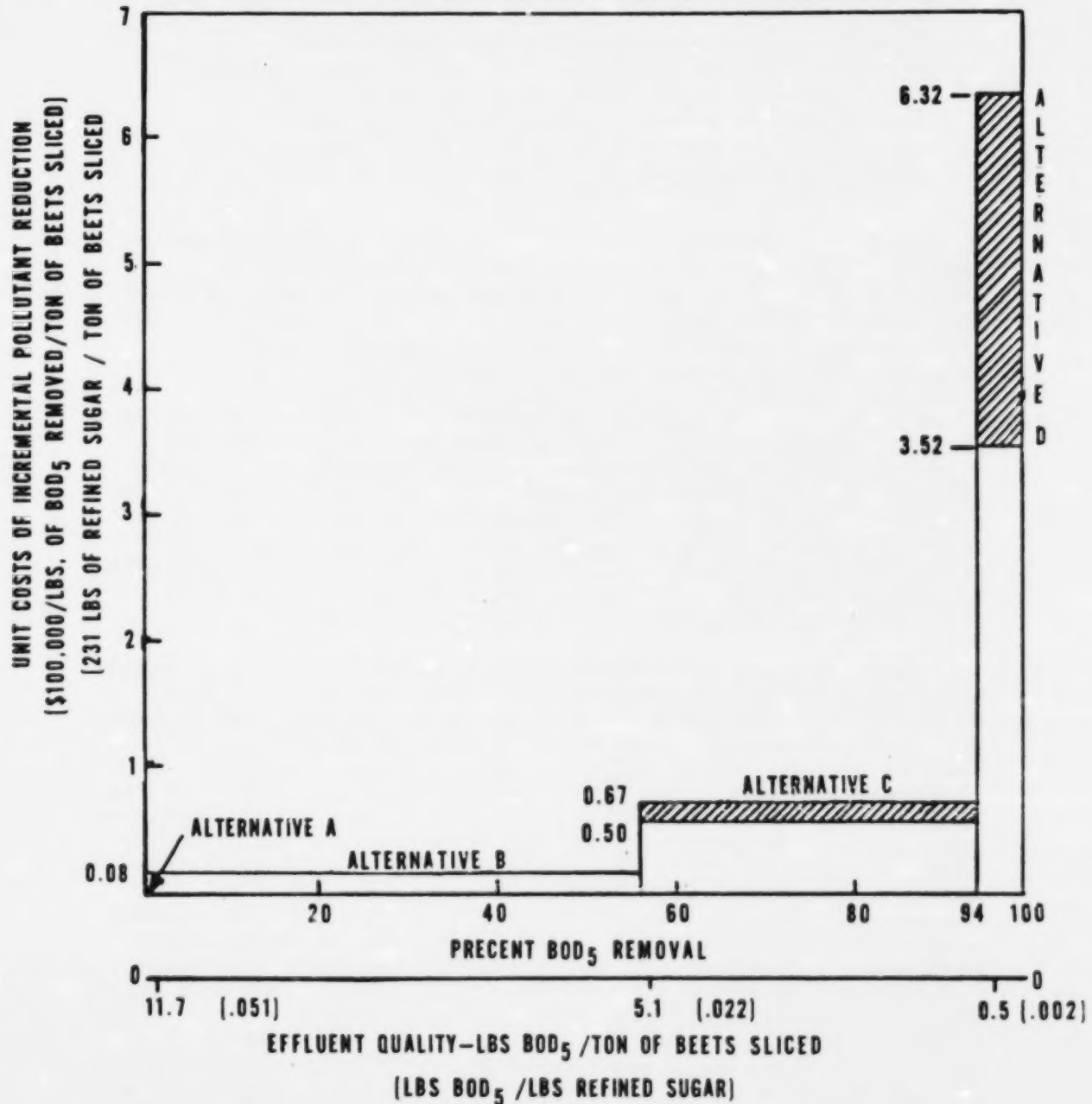
TOTAL COST EFFECTIVENESS RELATIONSHIP FOR COMPLETE LAND DISPOSAL
WITH NEEDED LAND LOCATED ADJACENT TO PLANT SITE



LAND COSTS ATTRIBUTED AS \$2000 PER ACRE INCLUDING POND CONSTRUCTION
AND INFILTRATION CONTROL MEASURES. BASED ON 3600 TON PER DAY
(832,000 LBS OF REFINED SUGAR PER DAY) PLANT, 100-DAY CAMPAIGN AND
1/4 INCH/DAY INFILTRATION RATE.

FIGURE 2

UNIT COST EFFECTIVENESS RELATIONSHIP WITH LAND FOR WASTE WATER DISPOSAL
LOCATED ADJACENT TO PLANT SITE AND PRESENTLY UNDER PLANT OWNERSHIP



¹ LAND COSTS ATTRIBUTED AS \$2000 PER ACRE INCLUDING POND CONSTRUCTION AND SEEPAGE CONTROL MEASURE 3600 TONS PER DAY (832,000 LBS REFINED SUGAR PER DAY) PLANT, 100 DAY CAMPAIGN AND 1/4 INCH PER DAY INFILTRATION RATE.

It is thought to be a useful tool for validating subcategorizations: factors such as size, location, and age often do not sufficiently affect the nature of the raw waste load, the appropriate treatment system, or its effectiveness but can appear in the form of disproportionate cost.... Moreover, plant closures were also a surrogate measure for EPA's impact on the competitive structure of the industry. Finally, plant closures is a tangible index (and directly related to unemployment) which is much easier for non-economists to appreciate than price changes, trade effects, changes in cost structures, or other conventional economic measures.*6

There is, however, one other widely used and commonly understood measure of economic impact--dollar costs. Although all the necessary data are provided, and detailed cost calculations were performed in order to determine the plant closure possibilities, neither document contains estimates of the actual costs of going from the present degree of control to that of any of the alternatives considered. Costs cannot substitute for plant closings, but they do summarize some kinds of data not present in the plant closure estimates alone. It is, therefore, strange, that having developed the costs in some detail, EPA did not present them as part of the analysis. Detailed cost data were considered internally, however. Several individuals from both the Effluent Guidelines and the Economic Analysis Divisions recalled working up costs for particular plants and using this data to help in resolving issues.

Nevertheless, the central issue in the economic analysis is comparison of the consequences of plant closings for different alternatives. Table 10 shows one such comparison prepared by EPA (the same data is also presented in other ways in several other tables). The results for plant closures in Table 10 differ significantly from those in the analysis presented in Section V. Comparison is difficult to make easily, in part because EPA does not provide a single best estimate of the number of closures, nor do they define the probabilities which "high," "low," and "maybe" represent. It is, however, possible to convert the closure analysis to the same terms, and, when this is done, EPA's estimate of closures are lower for the baseline condition and higher for every alternative than in the above analysis. This results from differences in methodology and differences in data availability. EPA, rather than developing plant by plant estimates, initially used a series of classes of plants, each typified by a model plant. The likelihood of closure for each individual plant was then further modified by looking at the characteristics that differentiated the individual plant from the model plant. The initial results based on only the model plants are quite

TABLE 10

CLOSURE PROBABILITY ESTIMATES UNDER VARIOUS POLLUTION CONTROL ALTERNATIVES FOR 1977

Alternative Probability	Baseline Condition			0.5 lbs. BOD 1977			0.5 lbs. BOD 1977 or Land Available Concept			Zero Discharge for all plants 1977		
	High	Maybe	Low	High	Maybe	Low	High	Maybe	Low	High	Maybe	Low
Region I	0	0	5	3	2	0	3	2	0	5	0	0
Region II	0	0	4	0	0	4	0	0	4	0	2	1
Region III	1	3	10	1	3	10	2	4	8	5	3	6
Region IV	1	1	9	1	1	9	2	1	8	2	1	8
Region V	0	0	2	0	0	2	0	1	1	0	1	1
Total	2	4	30	5	6	25	7	8	21	12	8	16

Source: U.S. EPA, Economic Analysis of Effluent Guidelines: Beet Sugar Industry.

similar to those in the analysis given here, the differences being readily explicable through differences in methodology. EPA's final estimates, however, are quite different; using the same method of defining the best estimate as for the analysis given here, EPA estimates that elimination of discharge would cause 14 additional closures over baseline conditions whereas the estimate given here is 6.5. The chief reason for this difference is that EPA introduced into their estimates a set of non-quantitative business factors, such as conglomeration and cooperative purchase possibilities not considered in the analysis here. As a result the EPA analysis may well represent a more accurate estimate: it was not used in the analysis here because inadequate data was presented to reproduce this portion of EPA's analysis.

The Economic Analysis Division felt that the resulting plant closure impacts were unacceptably large. A requirement of elimination of discharge could possibly close up to half of the plants in the industry. Because this industry was one of the pilot studies, and because the economic impacts were so significant, it seemed particularly important to establish that economic impacts could be a reason for arriving at a different system of levels of control or subcategorization.

To forward these views, the EAD took several types of action. First, an effort was made to produce the best possible analysis of the economic impacts of the regulation. Second, an effort was made to recruit support from other divisions of EPA. The most important in this respect, as reported to me, was the Permit Division, which was encountering problems with some beet sugar plants, and saw the need for some other approach to the guidelines. The Permits Division also reviewed the possible effects on water quality of alternative levels of control on a plant-by-plant basis in order to see how much high levels of control seemed to matter. The Economic Analysis Division interpreted the results of this analysis as favorable to their view that the less stringent guidelines had no great effect on water quality. Interestingly, the same type of data is interpreted in the Administrator's Briefing Package as unfavorable to less stringent guidelines. Finally an opinion was sought from the Office of General Counsel concerning the legal validity of using adverse economic impact as a basis for subcategorization. He ruled that it was an acceptable basis. (The Effluent Guidelines Division told me that they had never argued that it was not a valid ground for subcategorization; they felt that the problems were with the accuracy and not the potential importance of the economic impacts.) It was reported to me that ultimately this issue was decided by the Deputy Assistant Administrator for Water Programs. The Economic Analysis Division felt that the key to deciding the issue had been

that they were able to present a very high quality analysis and to show that their preferred regulation (.5 pounds of BOD per ton of beets sliced for BPT) had significantly lower cost and impacts without a significant adverse environmental impact. The end result was that BPT was redefined as not requiring complete recirculation of barometric condenser water for any discharger.

BAT remained a requirement of elimination of discharge, except for plants below a given size (which included all plants presently practicing no recycling whatsoever) or with soil filtration rates of less than or equal to 1/16 inch per day. These plants were required to reduce their BOD loads by 10 percent by 1983. It is suggested in the technical and economic documents that this can be done costlessly through in-plant controls and innovative processes. This type of reduction was recommended by industry and ESWQIAC as an alternative for plants not meeting elimination of discharge.

The primary purpose of the policy analysis presented in Section V is to clarify the issues involved in deciding upon the levels of control and degree of subcategorization. In this light, it is interesting to note that both that analysis and the more informal methods used by EPA led to a focus on many of the same issues. The basic issue, as seen by EPA, was that of the relative practicality and feasibility of high levels of control in this industry versus a perception of strong economic impacts. The explicit analysis leads to a focus on the same issues. Even including the full costs of plant closures, the cost of BOD control in this industry seems relatively inexpensive. On the other hand, the industry's unusual economic situation means that these costs take singularly undesirable forms; they cause plant closures and unemployment and are unusually highly concentrated on a small number of economic actors. Many within EPA saw the same sources of uncertainty as described in the explicit analysis. EPA felt that the focus on plant closures could in part substitute for more formal cost-effectiveness analysis, and, for this case, the conjecture seems to be borne out. It is difficult to find alternatives implementable under the Act that can achieve degrees of BOD removal equal to those considered by EPA at significantly lower costs.

The question of whether a more explicit analysis presents the issues more clearly can have only a subjective answer. I found that from a reading of the record assembled by EPA, the arguments for weaker standards seemed more strongly presented. They were backed up by detailed arguments and the relatively quantitative presentation on the number of plant closings. The opposing case was based largely on assertions of "practicality" and "feasibility." These terms are too vague to present a convincing case. They are inherently value-laden and present little data that

would allow one to formulate one's own judgments. By explicitly using even a very simple measure of benefits such as BOD reduction, it becomes easier to attach one's own meaning to the question of feasibility. In this case, the argument for more stringent standards becomes more convincing; BOD control is relatively inexpensive in this industry. Further, many of the industry arguments that the cost of control was underestimated could be accepted and the costs of control would still be relatively low for many plants.

The larger question of whether a more explicit analysis would have altered the decision process in any fundamental way is essentially speculative. There are, however, two areas in which it seems to me a more explicit analysis might have had major effects. First, consistent quantitative evaluation of consequences would almost inevitably lead to greater comparisons of cost effectiveness between limitations for different industries, and may have forced a clearer definition of priorities. From the present record, it is virtually impossible to compare different regulations in terms of incremental or average costs, degree of technology forcing, or importance attached to severe economic impacts. By making such a comparison possible, and relatively simple, it becomes far more likely that more consistent and cost-effective policies would have been adopted. A more explicit analysis, if made public, would have encouraged greater participation by groups other than industry, and more effective data contribution by industry. The present public record requires enormous patience and effort to determine the precise consequences of a given alternative. It is thus virtually impossible for environmental groups or industries to determine which limitations are excessively lenient or stringent. It is also difficult to easily determine what EPA viewed as the fundamental issues in any given case. Environmental groups might have taken a greater interest in this otherwise obscure regulation had they known that it would set precedents for determining the role assigned to such economic impacts as plant closings. Although environmental groups may not have been able to question the data in the plant closure analysis, they could have provided a useful perspective on the question of the relative importance of such closures. Industry also could have been given a clearer idea of what kinds of differences in costs would be large enough to affect EPA's considerations.

These possible advantages of more explicit analysis carry with them certain disadvantages. One of the disadvantages is that of additional time requirements. The simple production of the analysis would have required little more time than was in fact used. As noted, EPA developed all of the data necessary to complete such an analysis. The additional time requirements would rather have been before

the analysis started and after it was completed. They would have been caused by the need for explicit definition of approach at every stage. The approach and methodology developed by EPA, which has been criticized here as being too vague, aroused enormous debate both within and outside of EPA. Many aspects of it were to be challenged in court. A more specific set of initial directions would have inevitably led to far more debate, and would have taken more time. (The National Commission on Water Quality spent over a year on the task of determining precisely what consequences and definitions of consequences should be used in examining the impacts of this same legislation, and still showed remarkably little gain in consistency and comparability of sub-studies.) Defining and specifying consequences, even without the additional effort of defining what weights are to be attached to those consequences, is a difficult process that inevitably requires both political and technical inputs. At the conclusion of the analysis, the use of specified numerical consequences would tend to lead to more precise precedents with each decision. As it was, there was real debate within EPA as to the importance to be attached to economic impacts. Suppose a given regulation could be interpreted as setting precedents not just on whether plant closures should be considered but on precisely what weights should be attached to plant closures; the degree of diversiveness and the level at which the debate would have to be decided would be escalated, with almost certain consequences of increased time requirements.

B. The Dairy Industry

Because of the diversity of products even within a given subcategory, there was considerable difficulty in finding a suitable measure for a production parameter. Initially BOD input was suggested as the production parameter but the formulas used to calculate BOD input were simplified with each successive draft, largely in order to enable permit writers to more easily calculate the resulting limitation. All parties agreed to the pollutants selected for control, which were a fairly conventional choice of BOD, SS and Ph.

In order to aid in arriving at a decision on the proper level of control, EPA considered three levels of end-of-pipe treatment (no alternatives were considered as to level of in-plant control): 1) 90 percent BOD removal through secondary treatment; 2) 96 percent BOD removal through secondary treatment and sand filtration; and 3) no discharge through complete recycling. Tables were constructed showing both total and incremental BOD removal and costs, as well as cost per pound of BOD removed for typical small, medium and large capacity plants. One problem with these tables, however, is that the cost data include only operating and depreciation costs, with no cost of capital. Nevertheless

the format is closer to that suggested by a more explicit policy analysis than any analysis done for beet sugar. EPA initially recommended that all plants achieve level 2 for BPT, and that BAT be somewhat more stringent, relying on either improved in-plant controls or better operated treatment systems. In this recommendation, EPA seemed to rely less upon any cost-effectiveness criteria (some plants having cost per pound of BOD removed of up to \$1.62 per pound for BPT) than they did upon the average of the best rule. EPA noted that their cost estimate was probably high since it was based upon use of sand filtration and many plants could meet the BPT level of control through in-plant controls and secondary treatment alone.

There had been relatively little debate in the beet sugar industry as to whether the levels of technology could meet the exact limitations indicated; almost all of the debate had centered upon the question of subcategorization in order to reduce economic impacts. In the case of the dairy industry, serious questions were raised as to the ability of the indicated technologies to perform as well as EPA indicated. Industry seriously questioned the degrees of in-plant control required, and felt such levels could not be met except at exorbitant cost. EPA had treated these controls as essentially costless. The technical accuracy of EPA's initial proposals for suspended solids were questioned. Both industry and the Department of Commerce questioned requiring treatment clearly beyond secondary treatment for BPT.

EPA agreed to the industry's objection concerning the suspended solids requirements and the promulgated regulations were less stringent. To the argument that the degree of treatment was greater than secondary, several EPA officials pointed out that though the degree of treatment was higher, the quality of the effluent was not. EPA did not point out that, for most of the plants in the industry, the cost per pound of BOD removed was lower than for many municipal facilities. EPA made a series of changes in the final effluent limitations which had the general effect of giving less stringent requirements to plants with relatively concentrated wastes. The only explanation offered for these changes was "the limitations have been modified...to reflect a more uniform discharge quality among the subcategories." In the final versions of the technical analysis, the cost-effectiveness tables were dropped completely, and it was simply demonstrated that the plants designated as the best in the industry could readily meet the requirement.

For subcategorization, the basic issue was again one of whether smaller plants should receive a less stringent standard in order to reduce the number of plant closings. The issue was also noted by the EAD, the industry, ESWQIAC and the Department of Commerce. This was the subject of a

great deal of debate within EPA, and EPA sources consistently indicated that the basic decisions were the result of internal EPA considerations.

The Economic Analysis Division described their role here as one of a search for an acceptable alternative regulation that could relieve the extraordinarily high level of plant closings. EPA ultimately arrived at a recommendation of the use of an anaerobic system (septic tanks) plus a stabilization pond. The cut-off point between large and small plants for subcategorization purposes was determined as that point at which activated sludge systems became cheaper than the anaerobic plus stabilization pond system. The location of such a cut-off point, and even its existence, is the subject of a good deal of technical debate. The actual analysis and assumptions used are not publicly available. This change had the effect of reducing the number of anticipated plant closings from 573 to 102. Why it had this effect is somewhat perplexing, since as noted in the previous chapter, the economic analysis suggested that any investment whatsoever would cause almost the same number (573) of plant closings. Some of this may have been due to the large difference between the number of anticipated plant closings and the number of dairy processing plants which had applied for a permit. However, the major reason cited for the difference between anticipated plant closings and permit applications was a failure on the part of small dairy processing plants to apply for permits. This conclusion was based upon contact with the regional offices. Unfortunately, the revised economic analysis was not yet available.

VIII. FINDINGS AND CONCLUSIONS

The statute itself placed significant limitations upon the decision-making approach EPA could use in setting effluent limitations. Discouraged with past progress in water pollution control, Congress chose a radical new strategy, and took upon itself an important part of the task of weighing the benefits and costs of water pollution control programs. The result was a regulatory system which did not permit EPA to look at such conventional objectives as water quality or enhancement of uses of water in establishing regulations. Congress felt it had done this task in a rough way for EPA. However, the legislation did not clarify the details of strategy; it was not clear what sort of objectives EPA was to consider or how it was to consider them in writing particular limitations. For example, the Congressional intent clearly implied that the beet sugar industry should reduce its effluents, but there was virtually no clue as to how to decide whether 96 percent BOD removal should be considered adequate or whether 100 percent removal should be required.

Remarkably little time was given to EPA to decide these questions. The deadlines in the Act allowed virtually no time for either new data gathering or extensive thought on how to go about setting the regulations. Much of the divergence between EPA's approach to decision making in this case and the approach recommended by the Committee could be attributed to deadlines. Certainly many of the failures and gaps in the public record are directly attributable to time limitations. The ability of the record to explain decisions with clarity grows steadily worse as the deadline for promulgating the regulation approaches. Thus the draft recommendations are fairly carefully justified by the written record, while alternatives adopted in the promulgated regulations may never be documented anywhere. The failure to insure comparability of consequences among different regulations is also due in part to time pressures. It was difficult with the time and limited number of personnel available to write contracts that insured that all major issues would be considered; insuring that the consequences would be considered in comparable ways would have required enormously greater effort. Cost effectiveness might not have been a major consideration even with greater time, but it certainly seemed out of the question to EPA with the limited time available.

Nevertheless, time alone cannot explain the approach completely; time can be found for what is believed to be necessary. Of the several suggestions as to how the limitations might be set, EPA chose to emphasize the concept of the average of the best. This was probably the choice closest to the Congressional intent, certainly seems closest to the intent of Senator Muskie, one of the primary authors of the legislations, and was to be approved by the courts. It was not, however, the sole possible choice. Further, it is the choice that most clearly allowed the Agency to ignore a clear and general specification of objectives, and to avoid considering how to resolve the difficult question of subcategorization. Instead of encouraging the consideration of a set of alternatives according to prescribed criteria, it allowed the pretense that there was really only one possible alternative. The chief, though not the sole, mechanism set up for modifying this criteria was the economic impact analysis; and the chief concern of the economic impact analysis, at least in these two cases, was the impact of regulations on plant closures. This meant that neither the technical nor the economic analysis had a primary concern with a careful development of actual dollar costs or the relation of costs to effluent reduction.

EPA's data gathering effort was in some ways stronger than the approach that guided it. This was in part due to the variety of concerns in addition to the average-of-the-best concept that were used in developing data. For the beet sugar industry, EPA provided detailed data on how at

least five separate factors affected the cost of various levels of pollution control, thus providing a data base which permitted very detailed consideration of alternative subcategorization schemes. For the dairy industry, EPA provided full data on ranges encountered in performance of treatment systems in actual dairy operations, and provided detailed data on how costs varied by product types and by size of plant. However, some of this detail found little use in the actual analysis. For example, no explanation other than variations in the quality of management are given to explain differences in in-plant control of dairy wastes. Similarly, for the beet sugar industry, variations in BOD removal seem to be ignored in developing the recommendations, and the suggested removal rates change from page to page.

To help insure adequate review of data, EPA provided an unusual number of opportunities for comment, and carried out the decision-making process in a very open manner. In spite of this openness, however, almost all comment came from industry or sources very close to industry. The independent source set up by the Act, ESWQIAC, though providing some independent expertise, played a limited role. There were several reasons for this. First, many members of ESWQIAC were employed by, or worked closely with, industry, thus calling into question their status as genuinely independent reviewers. Second, many of the key questions concerning data simply required intimate knowledge of the industry, and no group of experts could be expected to have such detailed knowledge of every industry covered. As a result, there was a tendency for the Committee to focus on methodological issues and analysis. This was of little help to EPA since they had already formulated the basic elements of their methodology before ESWQIAC was even created, and many of the analytical comments were not a reflection of expertise, but of values and interpretations of the Act.

The absence of clear summaries of alternatives considered and their consequences, the lack of comparability of measures of consequences among studies, and the absence of clear information on how the limitations were to be implemented, all contributed to problems for outside review. The absence of clear summaries of alternatives considered and their consequences tended to mean that any outside party had to read large portions of every document, and meant that at least some technical background was necessary even to arrive at the most basic understanding of the decision in question. Lack of comparability among documents made it virtually impossible for environmental groups, or for that matter industry, to quickly discern situations where EPA requirements were unusually lenient or stringent. Failure to clarify how the limitations would be implemented added to confusion as to the importance of various issues. One simple example occurred in the Dairy industry: Fred Greiner

of the Dairy Industry Committee stated that his organization would never have given as much attention to the limitations if they had known that the BPT effluent limitations would not affect the pretreatment requirements. Rigor of enforcement could also affect one's interpretation of the importance of many data questions. Minor sources of variance from plant to plant would be highly significant if a discharger faced the prospect of going to jail if he failed to meet the precise limitation on his permit. If, on the other hand, installation of the EPA recommended technology accompanied by good operation were sufficient to meet permit requirements, then details of performance become less important. Similarly, from EPA's viewpoint, there is a difficult choice between highly stringent limitations that would force the best possible operations but be accompanied initially by massive violations, and less stringent limitations that would result in violations only for the worst operated plants in the industry, but which would not force high operational standards.

The openness of the decision-making process was also limited by the fact that major debates occurring within EPA were not always reflected in public documents. The clearest case is in the beet sugar limitations, where there was no outside notice that a major and precedent setting debate was occurring within EPA on the weight to be attached to plant closures for purposes of subcategorization. However, in later studies, when plant closures were seen as major issue, some notice of this fact did appear in the Federal Register.

The most obvious problem with EPA's analyses is lack of consistency in the two cases examined. Cost-effectiveness units differ in the two analyses. What are reported as costs vary from document to document, one containing only capital costs, the other at some points neglecting cost of capital. Plant closures reported in one document refer to plants which actually change in probability of closure; in the other, the plant closures merely represent slight accelerations of existing trends. This lack of comparability makes both general cost-effectiveness analysis and any assessment of priorities virtually impossible. In spite of these difficulties, however, the analysis of the individual regulations does a remarkably good job. The more formal analysis of the beet sugar industry done here suggests that EPA's perception of the major issues was accurate, and more surprisingly, that it would be difficult to find more cost-effective alternatives than those considered by EPA. The chief value of more formal analysis is that less subjective grounds than assertions of feasibility could be found to support arguments for more stringent standards. However, comparing the two industries raises more serious questions. Much higher costs were imposed on the dairy industry for BPT than were imposed on the beet sugar industry. It is not obvious why this should

be the case. It is also clear that both regulations cannot be cost effective if the same criteria of cost per pound of BOD removed is used.

One major possible benefit of more explicit analysis lies in its effect of encouraging more careful attention to priorities and to cost effectiveness. EPA can rightly point out that these were not primary concerns of the present statute, but this still raises a problem.

To explicitly require consideration of cost effectiveness would enormously increase the burden of proof on the Agency in producing regulations. In this case, EPA has demonstrated that cost effectiveness will not be considered unless explicitly required. This leaves Congress with a difficult problem in the future: there may be no way of introducing a concern for cost effectiveness without introducing it to an excessive degree.

NOTES

- 1 I wish to thank the many individuals who consented to interviews in connection with this study. From EPA Allen Cywin, Sweb Davis, Robert Dröllinger, Ernest Hall, Judith Nelson and John Riley all provided valuable insights. David Carter of the U.S. Beet Sugar Association, Fred Greiner of the Dairy Industry Committee, and Martha Sager of ESWQIAC also provided helpful comments on their views of the decision process. Blair Bower of Resources for the Future, and Allen Cywin, Sweb Davis, David Davis, and John Riley of EPA provided comments on an earlier draft of this study (one which did not include the policy analyses of the Beet Sugar Effluent Limitations). Robert Dorfman suggested the policy analysis of the beet sugar effluent limitations and provided enormously valuable comments on a succession of drafts of that section. Eugene Seskin and Leonard Geonese also provided helpful comments on that section of this paper. Finally, I wish to thank John Harris for research assistance on all portions of this paper.
- 2 See National Research Council, Analytical Studies for the U.S. Environmental Protection Agency; Volume II, Decision Making in the Environmental Protection Agency, A Report to the U.S. Environmental Protection Agency from the Committee on Environmental Decision Making, Commission on Natural Resources, National Academy of Sciences (Washington, D.C.: 1977).
- 3 Ibid.
- 4 Federal Water Pollution Control Act sec. 301(b) (1) (A) 33 USC 1311(b) (1) (A).
- 5 FWPCA, sec. 301(b) (2) (A), 33 USC 1311 (b) (2) (A).
- 6 FWPCA, sec. 315, 33 USC 1325.
- 7 FWPCA, sec. 502(11), 33 USC 1362(11).
- 8 FWPCA, sec. 304(b), 33 USC 1314(b).

- 9 See U.S. Congress, Senate (1971) Federal Water Pollution Control Act Amendments of 1974 Senate Report 92-414, Committee on Public Works, (p. 44) 92nd Congress, 1st Session and U.S. Congress, House (1972) Federal Water Pollution Control Act Amendments of 1972, House Report 92-911, Committee on Public Works, 92nd Congress, 2nd Session, p. 101.
- 10 U.S. Congress, House, supra note 9, p. 101.
- 11 FWPCA, sec. 304(b) (a) (B), 33 USC 1314(b) (1) (B).
- 12 U.S. Congress, Senate, supra note 9, p. 50.
- 13 EPA, Legal Compilation: Statutes and Legislative History, Executive Orders, Regulations Guidelines and Reports: Supplement I: Water, Volumes I-III. (Washington, D.C.: 1973) p. 703.
- 14 FWPCA, sec. 304(b) (2) (B), 33 USC 1314(b) (2) (B).
- 15 U.S. Congress, Senate, supra note 9, p. 50.
- 16 For an extensive bibliography of such studies, see National Research Council, Water Quality Criteria 1972, A Report of Committee on Water Quality Criteria, Environmental Studies Board, National Academy of Sciences (Washington, D.C.: 1972).
- 17 Examples of such studies are reviewed in Kneese, Allen "Quantitative Comparison of Policy Instruments for Environmental Improvement," a background paper prepared for the Committee on Environmental Decision Making. The journal Water Resources Research also has published many examples of such studies.
- 18 See supra note 17.
- 19 EPA, supra note 13, p. 786.
- 20 Ibid., pp. 360-363.
- 21 For a full description of the working group-steering committee process, see National Research Council supra note 2, pp. 204-223. The procedures were somewhat abridged in this case, most effluent limitations were not required to go through formal steering committee review. Instead a "mini-steering committee" was used, consisting of a representative from the immediately affected divisions.
- 22 Zener, Robert, "The Federal Law of Water Pollution Control" in Dolgin and Guilbert, Federal Environmental Law, (St. Paul, Minn: West Publishing Co. 1974).

- 23 Letter from David G. Davis, Office of Planning and Evaluation, EPA to the author, June 24, 1976.
- 24 ESWQIAC, First Annual Report, Effluent Standards and Water Quality Information Advisory Committee, March 2, 1973 - March 1, 1974, (Washington, D.C.: 1974), p. 72.
- 25 Ibid., p. 74.
- 26 Ibid., p. 73.
- 27 Ibid., p. 72.
- 28 Ibid., p. 72.
- 29 One such method would be to note how raw waste loads correlate with various degrees of end-of-pipe treatment. If plant managers are economically rational, they will reduce in-plant waste until the marginal cost of in-plant controls is just equal to the marginal cost of end-of-pipe treatment.
- 30 Kneese, Allen and Lof, George O.G., The Economics of Water Utilization in the Beet Sugar Industry, (Washington, D.C.: Resources for the Future, 1968), p. 22.
- 31 Ibid., p. 108.
- 32 EPA, Supplement A to Development Document for Proposed Effluent Limitation Guidelines and New Source Performance Standards: Beet Sugar Segment of the Sugar Processing. Point Source Category (unpublished and undated).
- 33 Ibid.
- 34 Kneese and Lof, supra note 30, p. 110.
- 35 EPA, supra note 32.
- 36 Urban Systems Research and Engineering: The Distribution of Water Pollution Control Costs: The Municipal Industrial Interface. (Cambridge Mass.: 1975), p. 43.
- 37 EPA, Development Document for Proposed Effluent Limitation Guidelines and New Source Performance Standards: Dairy Production Processing Point Source Category. (Washington, D.C.: 1975).
- 38 EPA, An Economic Analysis of Effluent Guidelines, the Beet Sugar Industry. (Washington, D.C.: 1975).

- 39 EPA, Development Document for Effluent Limitation Guidelines and new Source Performance Standards: Beet Sugar Processing Subcategory of the Sugar Processing Point Source Category. (Washington, D.C.: 1974).
- 40 Foregone production may be taken up in one of four ways: through imports, through new capacity, through expansion of daily capacity in present plants, and through expansion of campaign length in present plants. Imports and expansion of campaign length in existing plants would have lower costs to the nation than production in plants likely to close. Building new capacity or expanding present capacity would have greater costs to the nation. This range of possibilities has been dealt with in the cost analysis by adding to the range for each alternative involving plant closings, a factor of plus or minus \$.30 per ton of beets processed.
- 41 See EPA, supra note 39.
- 42 See EPA, supra note 38. These values are obtained by extrapolating from model plant data provided by EPA.
- 43 Ranges given in EPA, supra note 39, were used wherever available. The range for BOD removal was estimated by the author and based upon the varying estimates of BOD removal noted in the various EPA documents. The range for costs of foregone production is from supra note 40.
- 44 For a distribution of this type, the variance is equal to 1.25 times the range squared divided by 12.
- 45 This figure is arrived as the mid-point between the figure for a normal distribution and the Chebychev inequality.
- 46 Letter from David G. Davis, Office of Planning and Evaluation, EPA, to the author, June 24, 1976.

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PRIMACY UNDER THE SAFE DRINKING WATER ACT

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The Safe Drinking Water Act (SDWA) was signed into law December 16, 1974 for the purpose of assuring that water supply systems meet minimum national standards for protection of public health. Legislation authorizing the Environmental Protection Agency (EPA) to regulate suppliers of drinking water had been introduced in Congress each year since 1970, but it took a report of dangerous chemicals in the water supplies of several major cities to arouse the concern of the public and Congress. Prior to the enactment of the SDWA, federal control of drinking water was limited to interstate carriers and then only upon the spread of communicable diseases. Most states, however, had adopted the federal drinking water standards as the basis for their own drinking water programs.

The SDWA requires that EPA set National Primary Drinking Water Standards to protect health to the extent feasible (taking technology, treatment techniques, and costs into consideration) and develop Implementation Regulations, to establish the minimum requirements under which states can qualify for the primary responsibility to administer and enforce the Act. This primary enforcement responsibility is referred to by EPA as "primacy." Until health related aspects of drinking water contaminants can be reviewed and primary standards established, EPA is required to establish and enforce Interim Drinking Water Standards.

Like the Clean Air Act (CAA) and the Federal Water Pollution Control Act (FWPCA), the SDWA establishes a policy that the primary responsibility for administration of the law should be given to the states. EPA is required to enforce the Act only when a state fails to carry out its responsibilities. There are, however, several barriers to the attainment of the goal that states enforce the Act. The Act requires that state programs meet certain minimum requirements to qualify for primacy, but many states' laws must be revised to provide state agencies with the necessary authority. Furthermore, many states are reluctant to take primacy unless adequate resources are also provided. Reaching the goal of state administration of the SDWA is important, because EPA has not been given the resources to implement the Act effectively if many states refuse to accept the responsibilities.

It was EPA's responsibility in 1975 and 1976 to design a program under the SDWA with an "appropriate balance of health protection and realistic implementation."¹ Standards for the supply of drinking water to the public must ensure

that public health is protected, and regulations for the administration of the Act must ensure that a capable agency enforces the standards.

I. REGULATION DEVELOPMENT PROCESS

The development of the regulations under SDWA is regarded in EPA as one of the best examples of careful compliance with the Agency's formally established procedures for decision making. These internal procedures are outlined in EPA Order No. 1000.6A, "Policy with Respect to the Standards and Regulations Development Process."² In theory, all the procedures listed in 1000.6A should be used in the development of regulations. It is, however, the rule rather than the exception that the process be abridged.³

A. Formal Decision-Making Procedures (In Theory)

The formal procedures used in drafting regulations are summarized below.⁴

The first step in drafting a regulation is to assemble an ad hoc work group composed of staff members from the various Agency offices. The work group is responsible for developing the regulations and supporting documents; however, there is no formal guidance for the operation of the work group. One EPA office takes the primary responsibility of coordinating the efforts and drafting the documents for the work group meetings.

The work group first prepares a development plan that outlines the purpose of the regulatory package, alternative approaches to be explored, a methodology to be followed, procedures to be used to ensure outside participation, and the schedule for the process.

The work group then drafts the documents for review within EPA. These documents include the proposed regulation, a technical support paper that contains background information, and an action memorandum that summarizes for the EPA Administrator the major uncertainties, policy issues, and probable objections to the regulations. If required, an environmental impact statement and an inflation impact statement are also included.

The next stage in the process is review by the steering committee. The steering committee is composed of permanent representatives from each of the major EPA offices and has a permanent committee staff. Review by the steering committee provides each part of EPA the opportunity to comment from its own perspective on the proposed regulations as they are developed.

Review by the Office of Management and Budget (OMB) and other interested federal agencies comes next. Only after the proposed regulations have cleared OMB are they signed by the Administrator and published in the Federal Register for public comment. (The continued use of OMB review is currently the subject of debate between OMB and EPA.)

After analysis of the comments, the work group revises the regulations, technical support documents, and action memorandum. The final regulations are then reviewed by the steering committee and OMB before promulgation.

B. Formal Decision-Making Procedures (In Practice)

EPA organized a work group for the development of the Implementation Regulations several months prior to the enactment of the Safe Drinking Water Act. It was probable that the legislation would pass, and EPA had been preparing to administer such a law for several years. The major distinguishing feature of the work group was its composition. At its first meeting, the work group decided to involve the states in the development of the Implementation Regulations through their representatives to the Conference of State Sanitary Engineers (CSSE).⁵ EPA also included representatives from the water supply sections of two regional offices.⁶

The development plan initially prepared for the work group on Implementation Regulations by the Office of Water Supply followed EPA's prescribed guidelines and was approved by the steering committee in August, 1974. The plan stated that:

Unrealistic regulations will mean failure or refusal of States to assume primary enforcement responsibility. Each requirement placed on the States should be supported on the basis that it is required by the Act, that it will lead to the objective of safe drinking water, and that the costs will be worth the benefit. For EPA to assume responsibility of a State program would be completely impractical.⁷

The plan also proposed that a committee, with representation from all work groups preparing regulations under the SDWA, write a single Environmental Impact Statement for all the drinking water regulations.

In developing the Implementation Regulations, the work group decided that it was important to consider the total cost of improving state programs, possible sources of funds, and, most importantly, a method for gradual implementation of the program over several years. This gradual start-up of

the drinking water program is the main theme of "National Safe Drinking Water Strategy Document: One Step At A Time," published by EPA in May, 1975. The strategy document was prepared by EPA's Program Evaluation Division of the Office of Planning and Evaluation with input from the work group. While it presented the general tenor of the Implementation Regulations, its main purpose was to alleviate the fears of the states that the SDWA would be a repeat of the NPDES permit program under the Federal Water Pollution Control Act.

The proposed Implementation Regulations were prepared after extensive consultation with the states. The steering committee approved the proposed regulations in July, 1975 with no significant modifications and the regulations were then submitted to OMB. The steering committee and the Office of Planning and Evaluation suggested that extensive review by OMB and other federal agencies was not necessary, and OMB concurred with the decision.⁸ The proposed regulations were signed by the Administrator and published in the Federal Register on August 7, 1975.⁹

After publishing the proposed Implementation Regulations, the work group received over 350 written and oral comments from about 30 sources.¹⁰ In light of these comments, several revisions to the proposed regulations were made. The revised regulations were approved by the steering committee in December, 1975. Again the regulations were reviewed by OMB. OMB found a few problems but resolved them without difficulty. The final regulations were promulgated January 20, 1976.¹¹

II. MAJOR ISSUES OF IMPLEMENTATION

The intent of Congress in passing the SDWA was to make the best use of state expertise and resources and to encourage states to take responsibility for implementation of the Act. The SDWA requires that EPA delegate authority to administer the SDWA to a state that meets five statutory requirements: (1) state has adequate enforcement procedures, (2) state has record keeping and reporting programs, (3) state has emergency plan, (4) state has standards no less stringent than the national standards, and (5) state has qualified variance and exemption programs.¹² EPA has the authority to expand and to define these five requirements by publishing regulations. The extent to which EPA would establish explicit requirements and expand on the provisions in the Act would determine how much flexibility a state would have in designing its program and would affect the state's decision on whether to seek primacy.

Meeting the requirements of the Act and EPA's regulations would not be easy for some states, but, more

importantly, many states agencies could not even apply for primacy unless they had the resources to administer the drinking water program. Therefore, the Act also provides for federal grants for those states that qualified for primacy. Because the resource requirements were so important, the regulations governing federal grants were developed in conjunction with the implementation regulations.

During the development of the Implementation and Grant Regulations, several EPA decisions caused major concern to the states and other interested parties. Decisions affecting requirements on state enforcement programs exemplify the struggle to keep EPA's regulations flexible. The development of grant regulations reveals the extent to which EPA would forego other goals in order to ensure that states have the money and, thus, the incentive and ability to seek primacy. Finally, the impact of the Implementation Regulations on the development of the standards shows the importance of a coordinated and well planned decision-making process.

A. Enforcement

The Safe Drinking Water Act requires that, in order to qualify for primacy, states must have adopted "adequate procedures for the enforcement of...state regulations."¹³ Under this directive, EPA initially proposed general requirements that state programs must have enforcement authority "adequate to compel compliance with the State primary drinking water regulations in appropriate cases."¹⁴ This authority was described more fully, but specific measures of the adequacy were not provided. As a result of public comment and advice from EPA's Office of Enforcement, the final Implementation Regulations,¹⁵ however, provided more specific guidance on the type of enforcement authority needed by states, such as authority to assess civil penalties and to enforce public notification requirements.

When preparing regulations concerning programs for enforcement, EPA was faced with a problem of how state programs should be developed. Environmental organizations were concerned that states would develop their programs without adequate public input. The SDWA requires that EPA decisions be preceded by a public hearing, but did not require states to follow similar procedures. EPA, therefore, also had to decide whether to extend public hearing requirements to state programs.

1. Decision to Make Civil Penalties "Comparable to" Rather Than "as Stringent as" the Federal \$5,000 Per Day Penalty

The preamble of the final Implementation Regulations explains that the requirements for primacy, with the exception of the requirement for state drinking water standards, are not technically speaking "primary drinking water standards" as defined by the Act but rather are implementation provisions.¹⁶ Accordingly, state enforcement provisions, such as penalties for violation of primary drinking water standards, are not required by law to be as stringent as their federal counterparts.

Under the SDWA, EPA is given authority to seek civil penalties for as much as \$5,000 per day for violations. No penalty level, however, is established in the law for state enforcement and EPA decided not to require states to have \$5,000 per day penalty authority. EPA's Office of Enforcement (OE) had urged that a specific minimum penalty requirement be imposed on states' programs and had stressed that the threat of a tough penalty was needed to encourage compliance by the suppliers of drinking water. OE agreed with the Office of Water Supply that it was crucial that a large number of states assume primacy.¹⁷ Insistence on penalty authority equal to the \$5,000 would preclude many states from qualifying for primacy. OE, however, insisted that the question of appropriate penalty levels for states assuming primacy should be reopened in the future in order to evaluate the effectiveness of the states' programs. In the final regulations, EPA, therefore, explained that state enforcement programs without penalties as stringent as \$5,000 per day would be judged in light of the state's overall enforcement authority. Requirements for stricter penalty authority could, in theory, be required in the future.

There was no in-depth review or analysis of how stringent a penalty had to be in order to be effective or whether a lower requirement such as \$2,000 would be acceptable to the states, whereas a \$5,000 penalty would not. Rather, OE believed that they had a good sense of state laws, state officials views, and effective penalty levels. The \$5,000 penalty was supported by OE primarily because it was the minimum civil penalty authority required of states that qualify for the water pollution permit program and because it was the penalty set out in the SDWA for federal enforcement if states failed to take primacy.

If authority to assess civil penalties of \$5,000 was not required, OE recommended requiring some lower, but specified, penalty level. The Office of General Counsel (OGC), however, argued that, if a penalty figure less than \$5,000 was required by the regulations, the state legislatures amending their drinking water acts would pick

this lesser penalty. Any state water supply agency desiring authority for \$5,000 civil penalties would have difficulty arguing for the higher penalty. Thus, if the regulation did not require civil penalty authority as stringent as \$5,000, it would be preferable to require that comparable penalty authority be part of state programs. Such a requirement could encourage states to adopt the \$5,000 figure, while not ruling out primacy for those state agencies that could not get such authority.

EPA had experienced difficulty convincing states to assume the implementation responsibility under the Federal Water Pollution Control Act partly because of the severity of the state penalty requirements. (Only about 27 states have been delegated authority to administer the NPDES permit program.) EPA did not want to add a penalty requirement that might impede state assumption of primacy under the drinking water act.

The states agreed with EPA's final decision not to require states to have authority to assess \$5,000 civil penalties. They believed that if a state could demonstrate that it had been able to enforce its regulations, even though its civil penalties were less stringent than those in the SDWA, it should be allowed to qualify for primacy. In a letter to EPA, a representative of the State of Washington, wrote, "To follow this path [of requiring \$5000 civil penalties] will mean, I am afraid, that many, probably most, states will be denied primacy until or unless they are able to pass new legislation."¹⁸ The primary tenet of almost all states' comments was that, in the spirit of encouraging states to assume primacy, it is appropriate to show deference to states' wishes whenever possible.

Public interest groups took the opposite view. The League of Women Voters and the Environmental Defense Fund commented that state enforcement provisions should be "as stringent as" rather than "comparable to" federal provisions. However, after the Water Supply Office convinced the enforcement office that the regulations must be kept flexible and that the requirement of comparable civil penalties was acceptable, the decision was not going to be changed by the comments of outside interest groups.

2. Decision to Require States to Have Authority to Enforce Public Notification Requirements

The SDWA requires that each supplier of drinking water notify persons it served when the supplier is in violation of the Act or regulations under the Act. EPA originally only provided for public notification in the proposed Interim Standards, which set out the drinking water standards and requirements for suppliers of water. However,

in formulating the final Implementation Regulations, EPA determined that an adequate state enforcement program must also include a requirement that the state enforce public notification provisions.

Under Section 1414(c) of the SDWA, an owner or operator of a public water system must give notice to the persons served by it of a failure on the part of the public water system to comply with any maximum contaminant levels, treatment techniques, testing procedures, or monitoring requirements prescribed by the Interim Standards. If the public water system is subject to a variance or exemption granted under the Act, the owner or operator must notify the public of the existence of such variance or exemption and any failure to comply with the requirements of any schedule or control measure prescribed by such variance or exemption. Notice must comply with EPA guidelines that, for example, require that a notice be made public in water bills, newspapers, or on television. The Act provides that any person who willfully violates notification requirements shall be fined not more than \$5,000.

When developing its Interim Standards, EPA received only two comments approving its public notification requirements. Most comments expressed opposition because the requirements would cause problems for suppliers or because the notification provisions were inappropriate for some types of water systems.

The states argued that, although the SDWA requires public notification and while notification, under some circumstances, is appropriate, care must be taken when it is applied. Specifically they commented that consumers should be notified only if there is an immediate and significant threat to public health. Scare tactics or overuse of notification could lead to public disregard. EPA responded to these comments by citing the House Report on Safe Drinking Water, which stated, "The purpose of this requirement is to educate the public as to the extent to which public water systems serving them are performing inadequately in light of the objectives and requirements of this bill."¹⁹ EPA agreed that the supplier should be given the opportunity to explain the deficiency and that the notice should not be just a flat statement that the system had failed to meet a requirement.

Oscar Adams, who was on EPA's work group, commented on the proposed Interim Standards on behalf of Virginia. He wrote, "The cost of giving public notice will be substantial. A recent notice of public hearing in the Washington Post cost the State Health Department \$319. An advertisement over three days could easily exceed the operation budget of a small utility."²⁰ EPA agreed and cut back on requirements for public notification for small

communities in the Interim Standards; however, EPA retained most requirements for notifications.

Citizen groups noted that the proposed public notification requirements did not distinguish between community water systems, such as cities and towns, and non-community or small systems, such as restaurants with their own wells. They argued that this distinction was necessary because the requirements for community systems were inappropriate and ineffective in the case of most non-community water systems. For example, persons in transit would not be informed of problems in the drinking water supplied by non-community systems since they do not receive a water bill. The citizen groups also pointed out that the legal notices required by the Act would not be easily seen or understood by the general public and, therefore, would not serve the intended purpose. EPA concurred with some citizen groups comments, and several revisions were made in the final Interim Standards.

While these changes were being made on EPA's Interim Standards, the work group on Implementation Regulations took up the problem of whether to add enforcement provisions for public notification in its regulations. In meetings of the work group, state representatives had expressed a desire to keep public notification requirements out of the Implementation Regulations. The minutes of the fourth work group meeting read, "It was generally agreed that the section on public notification should not be included in the [Implementation] Regulations."²¹ As a result, in the proposed regulations, there was no requirement that the states adopt a state public notification enforcement program.

The ability of states to persuade EPA to accept initially their point of view can be contrasted with the citizen groups input. These groups did not have the opportunity to discuss notification requirements for the proposed regulations. Furthermore, because EPA's proposed regulations did not contain provisions for state enforcement of public notification, citizen groups failed to comment on whether public notification enforcement should be a part of state programs.²²

Despite the state opposition and the citizen groups failure to comment, EPA decided to add a provision requiring states to have authority to enforce public notification. This provision was added because the Agency had agreed to clarify what it meant by the terms "adequate enforcement authority" in the proposed Implementation Regulations. Again, EPA faced the problem of whether to require state notification provisions to be "as stringent as" federal requirements. EPA interpreted the law as allowing it to approve less stringent programs for states. Therefore, in

theory all water suppliers are subject to the requirements of public notification of the Interim Standards, but in practice, suppliers need only worry about the notification requirements of the states' programs, which could be less strict than those of the Interim Standards.

3. Decision Not to Require States to Hold Public Hearings

The SDWA provides that prior to taking certain actions, such as issuing standards or approving a state application for primacy, EPA must hold a public hearing. Similar hearings, however, are not required of states. EPA has authority under the Act to provide that no state could qualify for primacy unless the state's drinking water program provided for hearings. Such a requirement was one of the major recommendations of public interest groups but was viewed as an unnecessary and useless burden by the states.

In its proposed Implementation Regulations, EPA followed the guidance of the SDWA and provided for public hearings on its own actions but not on those of states. The comments received from citizen groups uniformly requested that EPA's own hearing provisions be improved and that states be required to conduct hearings in order to facilitate public participation in their programs. The Environmental Defense Fund (EDF) viewed the public participation provisions in the Federal Water Pollution Control Act as a model for the SDWA regulations. Specifically, EDF commented that public hearings should be required, as part of the state planning process, prior to submission of application for primacy to EPA and that public hearings must be reasonably timed, conceived, and structured.²³

The states emphasized their position that EPA's public hearings be kept to a minimum and that hearings not be required of states. The Conference of State Sanitary Engineers (CSSE) commented that public hearings are costly, time consuming, and in most cases, nonproductive. This position was discussed in the second meeting of the work group. Mr. Hutchinson of EPA's Atlanta Regional Office,

questioned the large number of public hearings included in the draft regulations. It was explained that the bill (H.R. 13002 which became the SDWA) requires an opportunity for public hearings in all instances where they are included in our draft regulations.²⁴

Thus, at that time, EPA appears to have decided to limit the use of public hearings to only those instances where the law required EPA to hold a hearing.

Oscar Adams, a state representative on the work group, represented the State of Virginia at the September 5, 1975 public hearings on the proposed Implementation Regulations. He expressed his views on the provision requiring EPA to hold public hearings prior to determining whether a state qualifies for primacy.

While this section is a requirement of the Safe Drinking Water Act, I fail to see how the public can make a meaningful contribution to a complex technical problem when intimate knowledge of the program will be necessary.²⁵

A few days after the hearing, Mr. Adams wrote additional comments in response to some of the testimony at the public hearing. He recommended that the suggestion to require public hearings for states be rejected for the following reasons: (1) the preparation of a state plan is the responsibility of the state, and not EPA; (2) holding a public hearing on the state program is not required under the SDWA; (3) public input will not constructively improve the state plans; (4) holding public hearings requires time and resources that can be used to greater advantage in other aspects of the program.

After the September 5 public hearing on the proposed Implementation Regulations, Oscar Adams also sent a letter to John E. Vought, Chairman of the Water Supply Committee of CSSE, explaining his concern about the comments presented at the hearing. He wrote:

There is a rumor prevalent among the EPA personnel to the effect that the League of Women Voters and the EDF were expected to submit very strong letters or comments urging more stringent regulations for state participation, and they want the states to hold public hearings on the state plan submitted in accordance with Section 35.615 and 35.600. Mr. Clark, who testified for the Coalition for Citizens for Safe Drinking Water, urged EPA to have...public hearings for citizen input especially on emergency plans.

Talking to Victor Kimm [EPA's Deputy Assistant Administrator for Water Supply] after the hearing leads me to believe that EPA would be hard pressed to deny the requests from EDF and the other environmentalists unless there were some testimony from states objecting to more stringent regulations and the additional public hearings. I believe CSSE must show some more interest or we will be stuck with another bunch of unnecessary and useless requirements.

I am going to submit an additional comment. I will object to additional public hearings and cite again the need for flexibility. Victor Kimm was very interested in getting some positive comments in the record as to what is right with the regulations as well as adverse comments.²⁶

John Vought sent a memorandum to the members of the CSSE urging them to speak out against more stringent regulations for public hearings and to submit supplementary comments to EPA during the extended comment period.²⁷ At the request of public interest groups, EPA had extended the period for public comments on the proposed Implementation Regulations. Until the EPA hearing, the states had thought it unnecessary to comment on public hearings, because state representatives had expressed their concerns while the regulations were drafted.

EPA revised the public hearings sections for the final regulations in several ways. These changes, however, only applied to the EPA hearings already required by law. The action memorandum for the final regulations noted that a "noteworthy change is [a provision] for increased public notification of public hearings and [for] a positive mechanism for inspection of material."²⁸ The League of Women Voters had recommended both of these changes in their written comments on the proposed Implementation Regulations.

EPA was willing to impose stricter hearing requirements on its own actions because it believed in the importance of public participation and because it could afford to bow to the desires of the citizen groups. EPA did not, however, require states to hold public hearings. In response to the suggestions for the addition of public hearing requirements for states, EPA said, "We do not believe further changes are desirable when the possible value of added public participation is weighed against the probability that it will result in failure of several States to desire primacy."²⁹

B. Grants

The Grant Regulations under the SDWA provide a formula for the allocation of federal funds to the states, procedures for grant applications, and restrictions on the use of the funds. The regulations were developed and promulgated simultaneously with the Implementation Regulations, because federal grants are a key factor in the states' decisions on whether to seek primacy. The primacy requirements add new burdens to almost all state programs, and, even if state agencies with responsibility for drinking water desire to have primacy, many governors and state

legislatures would be unwilling to allocate additional state funds to water supply programs.

1. Decision to Allow the Use of Federal Funds for Routine Monitoring

In the Interim Standards, EPA established routine monitoring requirements for each water supply system.³⁰ EPA believed that it was clearly the intent of Congress that water supply systems provide routine monitoring at their own expense and pass the added expense on to the consumer.³¹ Therefore, the initial draft of the Grant Regulations excluded routine monitoring as an allowable expense of federal funds by a state program. Because states often provide the monitoring for some systems and because they wanted no such restriction on the grants, EPA reversed its position prior to issuing the final regulations.

The minutes from the fourth work group meeting illustrate the states' concerns. William Staub, a state representative on the work group, said that he "believes that the public water systems, particularly the smaller systems, will be financially unable to assume this [routine monitoring] responsibility."³² He also pointed out that the monitoring provisions would require a large expenditure of resources to train sample collectors. As a result, in a later draft of the proposed Grant Regulations, the section on allowable costs was changed to permit states to spend federal funds on laboratory work for public water systems during the first two grant years, but not for subsequent years. The change, however, did not satisfy state representatives who believed that no time restrictions should be placed on the states. They argued that no specific language in the Act required water systems to provide routine monitoring.

The July, 1975 action memorandum, which accompanied the proposed Grant Regulations, offered four alternatives concerning the use of grant funds for routine monitoring: (1) prohibit the use of grant funds for routine monitoring, (2) allow the use of grant funds for routine monitoring without suggesting any further change, (3) allow the use of grant funds for routine monitoring at the present time; however, stress the legislative intent and encourage the states to shift responsibility for routine monitoring to the suppliers as soon as feasible, and (4) allow the use of grant funds for routine monitoring for the first two years of the grant program. The Water Supply Office argued against alternative four stating, "The intent of the Safe Drinking Water Act is to make the supplier of water responsible for this monitoring.... This alternative will not be in accordance with this intent for two years."³³ The office was arguing that a specific two-year deadline on this

provision would even encourage those states that did not do routine monitoring to take responsibility for monitoring. In contrast, alternative three, while not prohibiting the use of grant funds for routine monitoring, stressed the Congressional intent to make the supplier of water responsible for costs related to the primary standards. EPA selected the third alternative and eliminated restrictions on the use of grant funds for monitoring because it "accommodated the strong preference of several States for avoiding restrictions on State monitoring services."³⁴ EPA recognized, however, that its line of reasoning for not choosing alternative four was questionable, if not fallacious.

Without initially establishing a cut-off date for the use of grant funds, pressure on the States and water supply systems to find alternative funding will be reduced and it may be many years before use of grants for this [routine monitoring] purpose will be ended.³⁵

In its comments on the proposed Grant Regulations, EDF stated,

[W]e strongly agree with EPA that monitoring costs should be borne by the supplier of water and not the state health department. Therefore, we urge EPA not to allow any routine monitoring costs to be assumed by the states after the second fiscal year of the program. Two years is certainly time enough for even small water systems to devise an adequate scheme to replace health department monitoring, especially since in many cases the best replacement is to have the sampling and testing done by the state on a fee-for-service basis. The practice of externalizing monitoring costs results in economic distortions which can severely hamper planning efforts. EPA should move quickly to remove this type of distortion.³⁶

The American Water Works Association (AWWA)³⁷ was in agreement with EDF on this point. The AWWA commented,

We agree that monitoring expenses should be borne by public water systems and, through rates, by the people they serve. The transfer of these expenses should pose no great problem for the larger systems, which would pay for the work through funding their own laboratories, contracts with private laboratories, or payments to state laboratories. For the very small systems, including the gas-station type, the problem will be considerably greater if the cost of monitoring runs \$500 per year or more as has been reported.

Nevertheless, we feel that some method must be found to spread the cost of monitoring among the people benefited by it, primarily through user charges.... 'Direct' payment is not only fair and equitable, but far less costly in the long run than financing 'indirectly' through taxes.³⁸

During their review of the draft of the final Grant Regulation, OMB also expressed concern over the use of grant money for routine monitoring. Routine monitoring is the single largest cost for state programs. EPA, however, convinced OMB that routine monitoring should remain an allowable state-program cost in the final Grant Regulations.

EPA reiterated in the final Grant Regulations that routine monitoring should eventually become the responsibility of public water systems, but, no limitation on the use of grant funds for routine monitoring was included. In the preamble to the Grant Regulations, EPA stated that it could, at a future date, restrict the use of federal funds for monitoring but added, "if experience later indicates that a restriction is desirable, States which provide routine sample analysis for public water systems will be given ample time to phase out their programs or find additional funding."³⁹

2. Decision to Permit the Award of Second Year Grants Within the First Year

At the third work group meeting, Mr. Oscar Adams of Virginia, expressed the opinion that the key problem facing the states is that "the total amount of grant money is too small to implement the requirements of the Act.... There is not much to be gained by quibbling about factors which will only result in small differences in a state's grant money when the state will be required to do a great deal more work than the grant will cover."⁴⁰ EPA was well aware that a large and reliable federal grant program would be a critical factor in states' decisions to accept primacy.

To help the states get additional funds, EPA had to reevaluate its interpretation of the SDWA. The law says:

No grant may be made to a State under paragraph (1) for any period beginning more than one year after the date of the state's first grant unless the state has assumed and maintained primary enforcement responsibility....⁴¹ (emphasis added)

This was originally interpreted by EPA to mean a second grant could not be given if a state had not accepted primacy. EPA would award a first year grant to state water supply agencies that expressed their intent to seek primacy,

but the law clearly implied that second year grants would be used to reward states that acted quickly to qualify for primacy. In the preamble to the final grant regulations, however, EPA points out that, even though the intent of SDWA may be to the contrary, the Act "does not prohibit the award of a second program grant to a state within 12 months of the first grant award, even if the State does not have primacy at the time."⁴² (emphasis added)

According to the December action memorandum on the final grant regulation EPA chose to award the second year grant within the 12 month period because "this is allowable under the specific wording of the Act...and this is a highly desirable alternative to avoid a funding gap."⁴³ EPA concluded that awarding the second grant even if a state had not assumed primacy would improve the ability of states to qualify for primacy and would provide added flexibility for the implementation of state programs. The final grant regulations made clear that in order to qualify for the second grant, a state must demonstrate that it is moving toward early assumption of primacy.

C. Standards

The SDWA specifically requires that states qualifying for primacy must have drinking water standards that are at least as stringent as the national primary drinking water standards. This is the only requirement for primacy that the Act clearly requires to be as stringent as its federal counterpart. Therefore, state agencies were concerned about the development of Interim Standards not only because the standards set the requirements for suppliers of drinking water in their states but also because the agencies could qualify for primacy only if their standards were equivalent or higher than the Interim Standards. (States will later have to revise their standards to meet the provisions of EPA's Primary Drinking Water Standards that will replace the Interim Standards.)

EPA's Interim Standards established maximum contaminant levels, monitoring and testing provisions, and requirements for record keeping, reporting and public notification. Because the maximum contaminant levels were based on the 1962 Public Health Service Drinking Water Standards, which had been adopted by most states, the contaminant levels received little criticism from states. The Environmental Defense Fund, however, sued EPA for not including maximum contaminant levels for certain dangerous substances found in the drinking water of several major cities.⁴⁴

More important to the states were the monitoring requirements of the Interim Standards. Virginia noted,

The proposed [Interim Standards] set forth requirements for monitoring which are in excess of those needed to protect the public health.... The amount of monitoring for pesticides can not be justified on the basis of public health since these pesticides are not normally found in drinking water except when there has been an accidental spill or overt contaminating of the water supply....*5

Furthermore, because many states performed the routine monitoring for certain water supply systems, new monitoring responsibilities would drain additional resources from the states. Finally, the states were concerned about the monitoring requirements as they related to small water supply systems. The states questioned the ability of small towns to finance the monitoring requirements of the standards. For instance, Oscar Adams said, "59 percent of the public water systems in Virginia serve 500 or less individuals."*6

The League of Women Voters recognized the problem of the smaller systems but commented,

The League does not believe that standards should be lowered or monitoring requirements reduced because of cost problems.... Attention clearly must be focused on legislation to provide federal support for state implementation of the Safe Drinking Water Act. In the interim, the variance and exemption procedures specified in the law should be utilized to permit water supply systems unable to meet the standards to gradually work toward their attainment.*7

The issue of monitoring requirements soon became a problem for the work group on Implementation Regulations and the work group on Interim Regulations. Unlike the provisions for public notification that could be more stringent for the federal requirements of the Interim Standards than for the state requirements in the Implementation Regulations, monitoring requirements for states programs had to be as strigent as the federal requirements. Thus, EPA was faced with the basic problem underlying the development of drinking water programs. The Agency had to balance the need to protect public health with the need to ensure that the Act was implemented. EPA reduced the monitoring requirements to what it believed were the minimum necessary to protect drinking water.

III. EPA'S DECISION-MAKING PROCESS

EPA's Office of Water Supply is proud of the way it resolved issues of implementation and is confident that it

took the appropriate measures to ensure that sound drinking water standards are administered by effective state and federal drinking water programs. With the luxury of enough time to prepare for the passage of the SDWA, EPA was able to gather background information on state programs, plan for implementation, and follow the internal procedures for the development of standards and regulations. In fact, most outside observers of EPA's drinking water program are pleased with EPA's performance, although they may vigorously criticize a few decisions.

The most distinctive feature of the development of the Implementation Regulations is the conscious attempt by EPA to develop a partnership with states. The formal involvement of states was an innovative approach, born of necessity. Maintenance of drinking water standards had historically been the responsibility of state and local drinking water departments. EPA clearly does not have adequate administrative resources to implement the type of program that applies to over 50,000 water supply systems. Finally, EPA had been severely criticized for the lack of state and local involvement under the clean air and water acts. EPA's attempts to allay states' concerns and to develop a flexible implementation program, therefore, seem to be justified.

The final results of EPA decisions under the drinking water act cannot be assessed until states have had an opportunity to develop their programs and until the drinking water standards have been implemented. A few conclusions, however, can be made about the internal process for and the outside constraints on EPA's decisions.

A. Internal Process for Decision Making

EPA has established an elaborate set of procedural requirements for the development of its standards and regulations. For the regulations under the SDWA, the Agency carefully followed these requirements. The procedures create a framework for gathering information and for involving necessary parties in the decision. The procedural framework also provides the foundation for analysis of the issues and alternatives in a decision; however, EPA has no formal guidance to direct an analysis for its decision making.

1. Analysis

A formal, or textbook, analysis for making decisions would involve a process that requires the decision maker to have a statement of objectives, an evaluation of each alternative solution, and a comparison of the alternatives

in terms of the objectives. Such an analysis might involve an elaborate determination and a careful balancing of the costs and benefits of alternative decisions, or be little more than a structured common sense thought process. In any case, a formal analysis provides a framework for discussion of the important issues.

The analytical process used for decisions on implementation of the SDWA was never formally described by EPA. There was, however, at least some attempt to structure the process. By simplifying its objectives, EPA's analysis of the problems became easy for the Agency and clear to observers.

EPA's major objective for the Implementation Regulations was to convince the largest number of states to seek primary enforcement responsibility. This goal is used numerous times to justify decisions. For example, in the decision on second year grants, EPA was willing to alter a previous interpretation of the SDWA because the goal of states acceptance of primacy might otherwise have suffered and because the Agency did not fear a suit challenging its interpretation.

During the development of the Implementation Regulations EPA never attempted to state explicitly what its objectives were. The objective of complete state delegation is, nevertheless, obvious, and EPA defined the problems it needed to solve in terms of this objective. For example, EPA evaluated the legislative authority of each state agency to determine which enforcement requirements could be required in the Implementation Regulation without conflicting with existing state programs. Likewise EPA continually measures the success of its implementation program by the number of states that have applied or planned to apply for primacy.

EPA's objectives for decisions on implementation of SDWA, however, should not be stated only in terms of maximizing the number of states seeking and qualifying for primacy. The Act provided specific restrictions in the form of the five requirements and allowed EPA to establish additional restrictions on primacy. Thus EPA's objective should have involved convincing the largest number of states to accept primacy under certain minimum conditions. Prior to the revisions of the proposed regulations, however, EPA made no attempt to formulate the minimum conditions in terms less vague than the statutory language. EPA also never seriously considered alternative objectives if states could not or would not meet the primacy requirements. Thus, there was no consideration of alternatives such as joint implementation, where an enforcement program would be shared by EPA and a state.

EPA's development plan had stated that "in discretionary areas, alternative proposed regulations may be required in order to evaluate the cost-benefit relationships" (emphasis added). The Interim Standards were, in fact, reviewed formally by an outside contractor after each revision. The costs to water suppliers of complying with the requirements of the standards were analyzed as each alternative set of requirements was drafted. No such detailed and formal analysis, however, was present for the individual decisions involved in Implementation and Grant Regulations. Thus, in EPA's decision to allow states to use federal funds for monitoring, there was little attempt to determine which suppliers of drinking water relied on state monitoring, which suppliers could not afford to do their own monitoring, and what percentage of federal funds would be used for state financed monitoring.

The amount of formal analysis needed for any decision is dependent on the complexity of the problem. Therefore, when EPA characterized its objectives in terms of a single goal, it limited the alternatives it must consider and reduced the need for elaborate analysis. An attempt by EPA to refine the objectives and allow for the consideration of the quality of drinking water would have been more consistent with the ultimate goals of the Act, but would also have required additional information and much more complex analysis.

2. Procedures

In making decisions under the SDWA, EPA made extensive use of its formal internal procedures for the development of standards and regulations. In general, the results were favorable; however, several procedural steps were of questionable benefit to the overall program.

a. Work Groups. The work group is the basic unit for the development of all EPA regulations, and, even when other procedures are bypassed, some form of work group is used. The work groups for the regulations under the Safe Drinking Water Act were the first to formally use representatives of state and regional offices. The use of regional employees appears to have gained widespread acceptance for future work groups in all areas of EPA, for, if nothing else, the regional offices seem extremely happy with having a more direct role in decision making.**

The further use of state representatives, however, is less certain. Even for other SDWA regulations, such as those for underground injection, the use of state officials has been criticized. State involvement is certainly needed more than that of other outside interest groups for the writing of regulations dealing with state implementation of

federal laws. States add new perspectives and information for many of the decisions. Formal participation by states, however, creates risks. Those outside parties not included formally in the decision-making process are likely to feel that their comments are not receiving equivalent consideration and they might be more skeptical and critical of EPA's decisions.

In addition, the states can apply a great deal of pressure on EPA to accept state proposals, especially when the program is designed to maximize state acceptance. Therefore, when EPA includes outside parties in the internal decision-making process, the Agency needs a statute, such as the SDWA, that provides specific criteria for EPA to use as a solid fall-back position. Congress, however, will have difficulty in providing EPA with the farsighted and effective legislation that is needed to permit the Agency to include states or other interested parties on work groups.

b. Development Plan. A plan to provide the initial strategy for each set of regulations and for coordination of all sets of regulations under one program is an important part of EPA's decision-making process. However, because a plan can not accurately predict the course of events as regulations are developed, it can become obsolete very quickly. Furthermore, unless the people who are developing regulations have participated significantly in the preparation of a plan, they are not likely to feel compelled to abide by it.

The development plan for Implementation Regulations suffered because of two problems: it lacked relevance to the issues that were actually important when the regulations were developed, and it was not prepared by those who were drafting the regulations. Therefore, while the plan stated that "Existing EPA regulation and experience concerning State programs and grants for air, solid waste and water pollution are to be reviewed,"⁴⁹ no serious examination of the problems of other implementation programs was performed.⁵⁰ Similarly, the drafters of the development plan envisioned a thorough environmental impact statement for EPA's entire set of drinking water regulations. Later, opposition was raised by those who would be involved in the drafting of the impact statement, and many regulations were exempted.

The development plan did serve a useful function at the outset when the work group members needed to understand the major problems and timing of the Implementation Regulations. The plan, however, did not provide the work group or those outside the Agency continuing guidance.

c. Strategy Paper. Planning, priorities, and coordination for drinking water regulations also were not

provided by the overall strategy document. The apparent purpose of the strategy paper on the SDWA, One Step At A Time,⁵¹ was not to give guidance to EPA's regulations, but to alleviate state concerns about the direction of EPA policies for drinking water. The paper was developed by EPA's Office of Planning and Evaluation and used in meetings with states to discuss the drinking water programs. The paper, however, was written with little participation from the water supply office. Therefore, while five alternatives for state-federal relationships under implementation programs were described in the strategy paper, the work group and the primary drafters of the regulations were not familiar with the alternatives and never seriously considered any alternative except full delegation of enforcement responsibility.

B. External Constraints on Decision Making

EPA's decisions are never totally the product of internal analysis and procedures. Instead, decisions must be responsive to a wide range of political interests and legal constraints. Interested parties have the right to participate in the decision-making process through their written comments or their testimony at hearings. Congress can control agency action both through the statutes and Congressional oversight. For decisions on implementation of the Safe Drinking Water Act, EPA had to be extremely sensitive to the concerns of the states which were often in conflict with the requirements of the Act.

1. Safe Drinking Water Act

In general, the SDWA provided a remarkably well-suited framework for the development of Implementation Regulations. The SDWA sets out five minimum requirements that states must meet in order to qualify for primacy. As long as the Agency's interpretation of the Act agrees with the intent of Congress, clear guidance in the statute strengthens the Agency's ability to administer the Act. Thus, the law provides the justification for EPA to require that state drinking water standards and monitoring provisions be as stringent as those of the federal program. The statute must, however, provide EPA with flexibility to mold a workable program. When Congress is uncertain of the requirement needed, it must rely on the Agency's expertise to establish the specific provision. EPA may even create the flexibility it needs where the provisions of the Act seem too strict. For example, EPA awarded second year grants to states that were developing their programs even though the Act restricts those grants to states who have already qualified for primacy.

EPA's ability to manipulate laws in ways that improve its programs, however, could be challenged in courts. For example, EPA's failure to comply with the statutory deadlines under the SDWA left the Agency open to a law suit. EPA missed the deadline to issue proposed Implementa on Regulations by two months. EPA explained that the two month delay was needed to obtain additional state review of the regulations. Final regulations were also several months late, partly because citizen groups had asked for an extension of the public comment period. Because neither the states nor citizen groups were unhappy with the short delays, EPA was not sued for its failure to comply precisely with the statutory language.

2. Congress

After enacting the SDWA, Congress left EPA alone to implement drinking water programs. Although there had been great concern in Congress over the discovery of harmful chemicals in the water supplies of major cities, the passage of the Act shifted the debate to EPA.

The process of oversight and amending the SDWA, however, is likely to begin in 1977 or early 1978. At that time Congress is likely to be faced with requests from states and EPA to greatly increase the federal grants for state programs, and alter the requirements for primacy to make it easier for states to qualify.

3. States

EPA succeeded in developing a valuable relationship with the states by placing state representatives on the work group and by holding meetings to allow states to discuss and comment on the drinking water program. EPA was, no doubt, aware of the problems they could have with states, and in March, 1975 they had their first major confrontation with the states at what Oscar Adams of Virginia refers to as the "Battle of Williamsburg." There the states won major concessions. Adams said that the states knew they had leverage to obtain their objectives, since they knew EPA placed major importance on states accepting primacy.

States generally were satisfied with their impact on the process through their representatives.⁵² The states actually submitted very few comments on the proposed Implementation Regulations until they were alerted by CSSE that citizen groups were likely to achieve some changes in the regulations. The success of the SDWA is now primarily the responsibility of the states, and it appears that well over half of the states will seek, and qualify for, primacy.

4. Citizen Groups

The Environmental Defense Fund had played an important role in the passage of the SDWA and continued to participate in the development of EPA's standards and regulations. Together with the League of Women Voters (LWV), EDF submitted comments and testified at public hearings on the Implementation Regulations. Both EDF and LWV were members of the Citizen's Drinking Water Coalition, a nationwide organization of consumer and environmental groups interested in drinking water. The Coalition developed a computerized system to provide information on drinking water to its members. It also evaluated the ability of states to administer the SDWA, and it submitted a tabulation of state laws to EPA. The Agency asked the Coalition to arrange meetings at which concerned citizens could be briefed by EPA on its drinking water program.

The citizen groups were not pleased that the states had been more involved in the decision-making process than they were, but they were generally satisfied that their points of view were considered. The groups have also expressed general satisfaction with the final Implementation Regulations.⁵³

NOTES

- 1 Preamble to Proposed Regulations on Interim Primacy Drinking Water Standards, Federal Register, Vol. 40, p. 11990 (March 14, 1975).
- 2 EPA Order No. 1000.6A, "Policy with Respect to the Standards and Regulations Development Process," October 14, 1975. The internal procedures are also set out in EPA's "Standards and Regulations Manual," December 6, 1974.
- 3 Interview with Walter Barber, Chairman of EPA's Steering Committee, February 11, 1976.
- 4 See, William F. Pedersen, Jr., "Formal Records and Informal Rulemaking," Yale Law Journal, Vol. 85 (1975), p. 38.
- 5 The question was raised in the first work group meeting whether total dependence should be placed on CSSE (representing mainly State Health Departments) for representative State participation, since recent growth and reorganization of State environmental programs had placed many programs outside the authority of State Health Officials. However, EPA decided that the Water Supply Committee of CSSE still represents the majority of the State water supply programs. EPA also concluded that every effort would be made to secure participation of all states.
- 6 According to Walter Barber, EPA plans to continue to include state and regional representatives on the appropriate work groups. Interview, supra note 3.
- 7 EPA, "Development Plan for State Drinking Water Supply Program Regulation" July 30, 1974.
- 8 According to Walter Barber, skipping, or at least abridging, this interagency review is not unusual. Interview, supra note 3.
- 9 Federal Register, Vol. 40, pp. 33224-39 (August 7, 1975).

- 10 This is in comparison to 3,500 comments received on the proposed Interim Standards.
- 11 Federal Register, Vol. 41, pp. 2912-33 (January 20, 1976).
- 12 Safe Drinking Water Act, 42 USC 300g-2 (Supp V, 1975).
- 13 Ibid.
- 14 Federal Register, Vol. 40, p. 33233 (August 7, 1975).
- 15 See, C.F.R., Vol. 40, Sec. 142.10(b) (6) (1977); Federal Register, Vol. 41, p. 2919 (January 20, 1976).
- 16 Federal Register, supra note 15, p. 2917.
- 17 Memorandum from the Assistant Administrator for Enforcement to the EPA Administrator, December 19, 1975.
- 18 Letter from James Pluntze, Supervisor, Water Supply and Waste Section, State of Washington, to John Cofrancesco, Water Supply Division, EPA, October 8, 1975.
- 19 House of Representatives, Committee on Interstate and Foreign Commerce, 93rd Congress, Report No. 93-1185 on HR 13002, July 10, 1974, p. 24.
- 20 Comments on Proposed Interim Drinking Water Regulations, from Oscar Adams, Virginia, April 25, 1975.
- 21 Minutes of the Fourth Meeting, EPA's State Water Supply Programs Work Group, March 13, 1975.
- 22 Interview with George Coling of the Environmental Defense Fund, January 30, 1976.
- 23 Comments on Proposed Implementation and Grant Regulations, from George Coling and Jacqueline Warren, EDF, September 29, 1975.
- 24 See, Minutes of the Second Meeting, EPA's State Water Supply Programs Work Group, August 28, 1974.
- 25 Comments of Oscar Adams at Public Hearing on Implementation Regulations, September 5, 1975.
- 26 Letter from Oscar Adams, Director, Division of Engineering, State Health Department of Virginia, to John Vought, Chairman, Water Supply Committee, Conference of State Sanitary Engineers, September, 1975.
- 27 Memorandum from John Vought to members of Conference of State Sanitary Engineers, September 16, 1975.

- 28 Action Memorandum from Assistant Administrator for Water and Hazardous Materials to the Administrator of EPA, December 12, 1975.
- 29 Ibid.
- 30 Federal Register, Vol. 40, p. 59571 (December 24, 1975).
- 31 Interview with Jim Warren, EPA Water Supply Division, January 27, 1976; See Action Memorandum from Assistant Administrator for Water and Hazardous Materials to the Administrator of EPA, July, 1975.
- 32 Minutes, supra note 21.
- 33 Action Memorandum, from Assistant Administrator for Water and Hazardous Materials to the Administrator of EPA, July 23, 1975.
- 34 Ibid.
- 35 Ibid.
- 36 Comments supra note 23.
- 37 The American Water Works Association was founded in 1881 to "advance the knowledge of the design, construction, operation, and management of water utilities." Its stated objectives include the solution of problems involved in the production and distribution of safe and adequate water supplies, so that the industry can render the best possible service to the public. Membership includes individuals such as water utility personnel, municipal officials, public health workers, engineers, scientists, manufacturers of products, etc.
- 38 Comments on EPA's Grant Regulations from the American Water Works Association, September 12, 1975.
- 39 Federal Register, supra note 11, p. 2912.
- 40 Minutes of the Third Meeting, EPA's State Water Supply Program Work Group, February 7, 1975.
- 41 Safe Drinking Water Act, supra note 12.
- 42 Federal Register, supra note 11.
- 43 Action Memorandum, supra note 28.
- 44 Environmental Defense Fund v. Train, No. 75-2224, (D.C. Cir., filed December 17, 1975).
- 45 Comments, supra note 20.

- 46 Ibid.
- 47 Comments on Proposed Interim Standards from the League of Women Voters, May 9, 1975.
- 48 Interview with Charles Severs, Water Supply Division, EPA Region VI, December 11, 1975.
- 49 EPA, supra note 7.
- 50 Interview, supra note 28.
- 51 EPA, "National Safe Drinking Water Strategy Document: One Step At A Time," May, 1975.
- 52 Interview with Oscar Adams, Virginia Department of Health, January 21, 1976; Interviews with Charles Foster and Floyd Williams, Texas Department of Health Resources, December 16, 1975.
- 53 Interview, supra note 22; Interview with Carol Jolly, The League of Women Voters, January 28, 1976; Interview with Carl Clark, Citizen's Drinking Water Coalition, January 22, 1976.